OmniPod®

Insulin Management System
Système de gestion de l'insuline

User Guide

www.MyOmniPod.ca

Contacts and Important Information

Use the spaces below to record important health and product information.

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Health Insurance

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Policy Number

Pharmacy

Name

Address

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OmniPod System Start Date: _____
PDM Model: CAT35E Serial Number: _____

Distributor:

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Customer Care:

Please call 1 855 POD INFO (1 855 763 4636).

When outside of Canada, please call 647-788-3132.

Visit www.myOmniPod.ca for additional information and resources.

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Introduction

Before You Get Started

Indication

The OmniPod Insulin Management System is intended for *subcutaneous* (below the skin) delivery of *insulin* at set and variable rates for the management of *diabetes mellitus* in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (*in vitro*).

Contraindications

Insulin pump therapy is NOT recommended for people who are either:

- Unable to perform at least four (4) *blood glucose* tests per day
- Unable to maintain contact with their *healthcare provider*
- Unable to use the System according to instructions

Do not use the integrated FreeStyle® Blood Glucose Monitoring System for:

- Testing on newborns
- Testing arterial blood
- Diagnosing of or screening for diabetes mellitus

This *User Guide* is intended for use only with PDM model CAT35E. To learn which version of the PDM you have, turn it over. On the back of the PDM, look for "CAT35E." If you see it, this is the correct *User Guide*. If you do not see "CAT35E" on the back of the PDM, please call Customer Care at 1 855 POD INFO (1 855 763 4636). When outside of Canada, please call 647-788-3132.

This device is intended for self-testing by the user.

This *User Guide* is periodically updated. Visit www.MyOmnipod.ca and www.MonOmniPod.ca to see the most recent version.

WARNING

If you are unable to use the System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the System properly.

WARNING

The OmniPod System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoRapid®, Humalog®, or Apidra®. Before using a different insulin with the OmniPod System, check the insulin drug label to make sure it can be used with a pump. Refer to the insulin labeling and follow your healthcare provider's directions for how often to replace the Pod.

WARNING

Please read all the instructions provided in this *User Guide* and practice the blood glucose testing procedures before using the System. Monitor your blood glucose with the guidance of your healthcare provider. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

NOTE

Screen displays shown in this *User Guide* are for illustrative purposes only and should not be considered suggestions for user settings. Consult with your healthcare provider to determine the appropriate settings for you.

You and Your Healthcare Provider

The contents of the OmniPod® user manual are not intended to replace or substitute the advice of your physician or other qualified healthcare professionals. You should speak to your own healthcare professional, who is the best source of information regarding your own health related questions. Absolutely no information contained in the OmniPod® user manual should be construed as taking the place of your physician's or other qualified healthcare professional's advice.

Work with your healthcare provider to establish diabetes management guidelines and settings that best fit your needs. These may include:

Insulin-to-Carbohydrate Ratio: Number of grams of carbohydrate covered by one unit of insulin. For example, if your *insulin-to-carbohydrate ratio* is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

Correction or Sensitivity Factor: How much one unit of insulin will lower blood glucose. For example, if your *sensitivity factor* is 2.8, one unit of insulin will lower your blood glucose by 2.8 mmol/L.

Target Blood Glucose Value: The blood glucose level you want to achieve. For example, you may want to keep your blood glucose close to 5.6 mmol/L.

Duration of insulin action: The length of time that insulin remains active and available in your body after a bolus.

Your individual needs influence the initial settings you and your healthcare provider will enter into the Personal Diabetes Manager (PDM) during setup (see Chapter 2, Getting Started).

Your healthcare provider must help you enter these initial settings. Soon you will enter and change your own settings with confidence and ease. The OmniPod System is more user-friendly than most electronic devices you use every day. In fact, technology is what makes the OmniPod System so easy to use.

Your healthcare provider is a valuable resource. You will rely on him or her for a lot of critical information about your OmniPod System, especially during the first few weeks and months. When you have questions about diabetes management after starting on the OmniPod System, do not hesitate to talk with your healthcare provider. For nonmedical emergencies or for technical questions about your OmniPod System setup or operation, you can call Customer Care 24 hours a day, 7 days a week.

Customer Care:

Please call customer care at 1 855 POD INFO (1 855 763 4636). When outside of Canada, please call 647-788-3132.This user guide is periodically updated. Please visit www.MyOmniPod.ca and www.MonOmniPod.ca to see the most recent version and to find other helpful information.

Your Role: Safely Using the OmniPod System

Your healthcare provider will give you all the tools and training you need to be successful with the OmniPod Insulin Management System. However, in the end, your success depends on YOU. You must become actively involved in your own diabetes management to enjoy the outstanding control, freedom, and flexibility that is possible with the OmniPod System.

Being actively involved means:

- Frequently monitoring blood glucose levels
- Learning how to operate your OmniPod System and practicing proper techniques
- Visiting your healthcare provider

If you are having symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this *User Guide*, call your healthcare professional.

Do NOT attempt to use the OmniPod Insulin Management System before you receive training from your healthcare provider. Inadequate training could put your health and safety at risk.

About This User Guide

Conventions and Terms

Convention/Term	*Meaning*
Bold	Names of buttons, soft keys, menus, and screens are in **bold**.
Italics	Words in *italics* are defined in the Glossary at the end of this *User Guide*.
Press	Press and release a button or soft key.
Hold	Keep pressing a button until its function is complete.
Menu	A list of options on the PDM. Options allow you to perform tasks.
Screen	Displays programming, operating, and alarm/alert information.
Button	A physical button on the PDM, such as the **Home/Power** button.
Icon	An image on the PDM screen that indicates a menu option or item of information. A table of screen icons appears in the Appendices.

Conventions and Terms

Convention/Term	*Meaning*
Soft keys	A row of three unlabeled buttons on the PDM whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing.

Symbols

Symbol	*Term*	*Meaning*
	Warning	Describes potential serious adverse reactions, or indicates conditions that could cause death or serious injury.
	Caution	Indicates conditions that could cause minor or moderate injury to you or damage to the device.
	Note	Provides helpful information.
	Tip	Offers a suggestion for successful use of the OmniPod Insulin Management System.

CHAPTER 1

Your New OmniPod Insulin Management System

Insulin Delivery with the OmniPod System

The OmniPod Insulin Management System is an innovative continuous insulin delivery system that provides all the proven benefits of *continuous subcutaneous insulin infusion (CSII)* therapy in a way no conventional insulin pump can. The System's innovative design and features allows you to live your life—and manage your diabetes—with unprecedented freedom, comfort, convenience, and ease.

The long-term health benefits of better blood glucose control are well known. Maintaining near-normal blood glucose levels can help you live a longer, healthier life with fewer diabetes-related complications. The OmniPod System also has many practical, everyday benefits, including convenience, freedom, flexibility, and ease of use.

Continuous insulin delivery most closely mimics the insulin release of a healthy pancreas. Since the landmark 10-year Diabetes Control and Complications Trial (DCCT), the long-term health benefits of maintaining near-normal blood glucose levels have been widely recognized.

Continuous *insulin* delivery at preset rates eliminates the need for injections and the interruptions that come with them. In addition, with the OmniPod System, insulin delivery can be changed with the press of a button to adapt to snacks or unexpected changes in daily routine. The OmniPod System is a great option for people with diabetes who require insulin.

The OmniPod System works much like the pancreas of a person without diabetes by delivering insulin in two ways:

- A small, constant, background supply of insulin (called a *basal rate*) is delivered automatically at a programmed rate, all day and night.
- An extra dose of insulin (called a *bolus*) can be delivered when you need it to match the *carbohydrates* in a meal or snack or to correct a high blood glucose.

1 Your New OmniPod Insulin Management System

How Does the OmniPod System Work?

The Pod is a small, lightweight, self-adhesive device that you fill with insulin and wear directly on your body. The Pod delivers precise, personalized doses of insulin into your body through a small flexible tube (called a *cannula*), based on instructions that you program into its wireless companion, the Personal Diabetes Manager. The cannula is inserted only once with each Pod.

The Personal Diabetes Manager (PDM) is a wireless, handheld device that:

- Programs the Pod with your personalized insulin-delivery instructions
- Wirelessly monitors the Pod's operation
- Incorporates a FreeStyle® blood glucose meter

With just two parts, you'll enjoy all the functionality and benefits of continuous insulin delivery and blood glucose monitoring. Plus you'll enjoy the safety, convenience, and freedom of:

No tubing

There is no tubing connecting the Pod to the PDM. You wear the Pod comfortably and discreetly under your clothes. You can carry the PDM separately in a backpack, briefcase, or purse. With the OmniPod Insulin Management System, you don't have to worry about snagging, tangling, or feeling tethered by tubing.

Automated cannula insertion

With the OmniPod System, you don't have to insert the *infusion set* manually or carry around a separate inserter. You simply press a button on the PDM and the Pod's automated insertion system safely and consistently inserts the cannula beneath the skin, virtually pain free. It then begins delivering insulin according to your programmed basal rate.

A fully-integrated design with blood glucose monitoring

With a fully integrated two-part design, there's no need to carry separate infusion sets, reservoirs, or inserters. It's all integrated into the Pod. With the PDM, you can check your blood glucose level using FreeStyle® blood glucose test strips, but without the hassle of carrying a separate blood glucose meter.

If you prefer to use another blood glucose meter, you can enter the readings manually into the PDM.

Suggested bolus calculation

Calculating bolus doses has never been easier. After you check your blood glucose, enter the carbs for your snack or meal. Based on your individual settings, the System displays a suggested bolus dose. You can accept the suggestion, change it, or cancel it.

Carb presets

To make carbohydrate counting easier, the OmniPod System includes "carb presets." You can enter your favorite foods, snacks, or entire meals as "carb presets." Presets contain the grams of carbohydrate in the food item or meal. Next time you eat this same food, you don't have to count the carbs; just select your carb preset and the System does the calculating for you. The System stores up to 36 carb presets.

Record keeping

Another convenient part of the OmniPod System is record keeping. Paper charts are useful, but sometimes they can be inconvenient to carry or use. The data storage system in the Personal Diabetes Manager (PDM) displays up to 90 days' worth of information. This includes blood glucose readings, basal rates and bolus doses, carbohydrates, and alarms.

Personalizing your System

You can personalize your OmniPod System in other ways, too:

- Enter and name basal programs
- Name and save temporary basal presets
- Add your own customized reminders
- Enter your name, phone number, doctor's names and numbers, and other emergency information

1 Your New OmniPod Insulin Management System

The Pod

The **Pod** (Figure 1-1) is applied to your skin with an adhesive backing, similar to an adhesive bandage.

Figure 1-1

The Personal Diabetes Manager

All Pod operations are programmed and controlled through the palm-sized **Personal Diabetes Manager** (**PDM**; Figure 1-2).

Figure 1-2

Buttons that program and control the OmniPod System

Button	*Action*
Home/ Power	Pressing and holding turns the PDM on and off. When the PDM is on, pressing this button displays the **Home** screen, from which you can choose a menu item or view the **Status** screens (shown later in this chapter).
Up/Down Controller	Pressing scrolls through a list of available menu options or numbers, so you can pick the one you want. Holding the button scrolls faster.
Soft Keys	Soft key labels and functions depend on the menu or screen you are viewing. The label appears on the screen directly above the physical button you press. **Select**, **Save**, and **Back** are just three examples of the soft key labels on your PDM.

Button	*Action*
User Info/ Support	Pressing opens a **User Info/Support** screen that displays additional information about the current screen you are viewing. The **User Info/Support** icon appears when additional information can be viewed. It may be displayed at the top of the screen, to the right of an event detail (such as a suggested bolus), or to the right of a record item (such as a BG history record). (See "Personal Diabetes Manager Icons" in the Appendix.) In addition, pressing and holding this button for 2 seconds enables a "bright mode" on the PDM screen.

Primary screens

Messages on the screen either:

- Tell you how the System is operating
- List menu choices
- Explain how to perform certain tasks

The System's primary screens are the **Status** screen (Figure 1-3) and the **Home** screen (Figure 1-4).

Figure 1-3

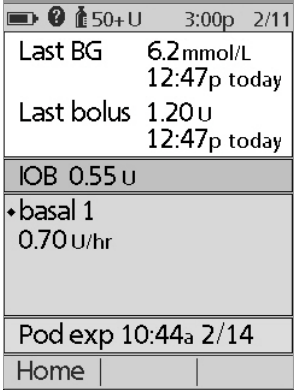
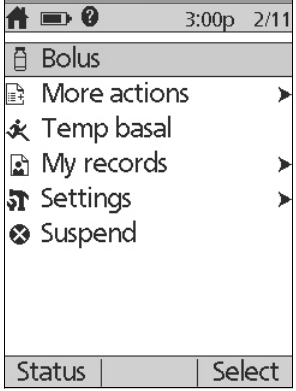


Figure 1-4



Status screen

Lists the System's current operating status.

From top to bottom, the **Status** screen displays:

- Time, date, and result of last blood glucose checked or entered manually
- Time, date, and total amount of last bolus delivered
- Amount of **insulin on board (IOB)**, if suggested bolus calculator is in use
- Name and rate of active basal program or temp basal program
- "Ext bolus," the amount of insulin, and the delivery time remaining if an extended bolus is being delivered
- "INSULIN SUSPENDED" if insulin delivery has been suspended
- Time and date when the Pod will expire

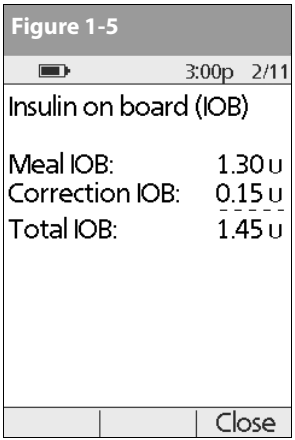
NOTE If a Pod has not yet been activated (as during Pod changes), the screen displays "No active Pod. Would you like to activate a Pod now?" (See Chapter 5, Using the Pod, for details on activating a Pod.)

Status support screen

From the **Status** screen, press the **User Info/Support** button to see details about the current

Insulin on board (IOB) in your body (Figure 1-5).

Figure 1-5



Home screen

Lists all the major menus (Figure 1-4 on previous page).

- **Bolus** menu to deliver bolus doses
- **More actions** menu to change the Pod, manually enter blood glucose readings, and assign and edit tags for BG readings that are less than 2 hours old.
- **Temp basal** menu to deliver temporary basal rates (This submenu does not appear if Temp basal is turned **Off** in **Settings**.)
- **My records** menu to review insulin delivery, blood glucose history, alarm history, carb history, and personal user information
- **Settings** menu to edit, enter, and name basal programs, temp basal, carbohydrate, and bolus presets, and to customize System settings
- **Suspend** menu to suspend, cancel, or resume insulin delivery programs

NOTE You can go to the **Status** screen at any time by pressing **Status** from the **Home** screen.

Safety Features

The OmniPod System's state-of-the-art design includes the latest safety technology. Its built-in safety features include:

Automatic priming, safety checks, and insertion

Every time you activate a new Pod, the System automatically primes and performs a safety check on the Pod, then inserts and primes the cannula (see Chapter 5, Using the Pod). Microprocessor technology makes it possible to complete thousands of safety checks in only a few seconds.

The OmniPod System also performs safety checks on the PDM. If it detects any problems in the PDM or the Pod—or in communication between them—it informs you with beeps and on-screen messages.

Rapid occlusion detection

An occlusion is a blockage or interruption in insulin delivery. If the OmniPod System detects an occlusion, it sounds a hazard alarm and prompts you to deactivate and change your Pod (see Chapter 10, Alerts and Alarms).

Alerts and alarms

For your safety, the OmniPod System provides a range of alerts and alarms to tell you that your attention is needed, or to warn you of hazardous situations.

See Chapter 6, Using the Personal Diabetes Manager, for a description of notifications and how to set them. See Chapter 10, Alerts and Alarms, for a list of safety alarms built into the OmniPod System and how to respond to them.

CHAPTER 2

Getting Started

Set Up the Personal Diabetes Manager (PDM)

If you are a first-time OmniPod System user, you need to meet with your *healthcare provider* for training and System setup before using it. To get a head start on learning about your new OmniPod System, review this *User Guide*. If you have a basic understanding of the System in advance, you will get more out of your training sessions.

WARNING

Do NOT use the OmniPod Insulin Management System until you have been trained by your healthcare provider. He or she will initialize the System based on your individual needs. Inadequate training or improper setup could put your health and safety at risk.

NOTE

Prepare and keep an emergency kit with you at all times to quickly respond to any diabetes emergency. For details, see Chapter 9, Living with Diabetes.

Chapter 6 describes the PDM options in detail. The instructions in this chapter are simplified to help you get started.

Turn on the PDM

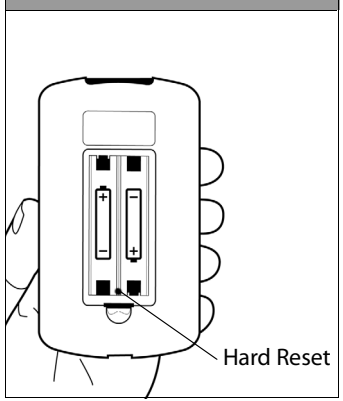
1. Open the battery compartment on the back of the PDM by pushing the compartment latch and lifting upward (Figure 2-1). No special tools are necessary.

Figure 2-1

2. Insert two (2) new AAA alkaline batteries into the compartment.

NOTE The diagram inside the compartment shows you which direction to insert the batteries (Figure 2-2).

Figure 2-2



CAUTION Do not use any other type of batteries than AAA alkaline batteries to power the PDM. Never use old or used batteries; the PDM may not work properly.

3. Replace the battery door.

4. Turn the PDM face-up. The PDM has begun to power on automatically.

The OmniPod Setup Wizard

The first time you turn on the Personal Diabetes Manager, the Setup Wizard comes on automatically. Although setup is easy with the Wizard, if you are a first-time user, your healthcare provider must guide you through the process. Setup takes only a few minutes and is easy to do:

- Use the **Up/Down Controller** buttons to increase or decrease a number or to move up or down a list.

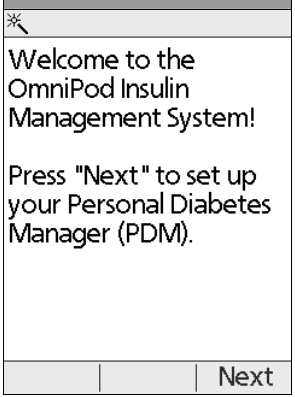
  NOTE Initial settings are "---" [blank] for target blood glucose value, insulin-to-carbohydrate ratio, correction factor, and duration of insulin action.

- Press the *soft key* labeled **Next**, **Select**, **Done**, or **Save** to continue to the next screen.
- Press **Back** to return to the previous screen.

NOTE You can adjust these settings later as your needs change or you fine-tune your OmniPod System. See "OmniPod System Options and Settings" in the Appendix.

The Wizard's Welcome screen (Figure 2-3) gets you started. Press **Next** to begin setting up your PDM.

Figure 2-3



Set date and time

1. Use the **Up/Down Controller** buttons to increase or decrease the time. (Press **12/24hr** if you prefer a different time format.) Then press **Next**.
2. Enter the current year, then press **Next**.
3. Choose the current month, then press **Next**.
4. Enter the current day of the month, then press **Next**.
5. Choose the date format you prefer, then press **Next**.

Enter basal settings

1. Choose a maximum *basal rate*, then press **Next**. (The default maximum basal rate is 3 U/hr.)
2. Choose the initial basal rate to use, then press **Next**.

   The initial basal program created with the Setup Wizard is named basal 1. You can change the name in the **Settings > Basal programs** menu (see Chapter 3, Understanding and Adjusting Basal Rates).
3. Press **Done** to confirm the basal program shown on the screen. To add more *basal segments* to the program, or to change the rate shown, see Chapter 3, Understanding and Adjusting Basal Rates.
4. To see the basal program as a list, press **List**. To return to the graphic view, press **Graph**.
5. Press **Save** to accept the basal program you have set.
6. Choose a *temporary basal* feature, then press **Next**. Choose **%** to show temporary basal rates as a percent increase or decrease of your current basal rate. Choose **U/hr** to show temporary basal rates in units per hour. Or choose **Off** to turn off the temporary basal feature. For details about setting temporary basals, see Chapter 3, Understanding and Adjusting Basal Rates.

NOTE You can add up to 7 basal programs and set 24 segments per program

Enter blood glucose sound setting and BG goal

1. To set the sound for the blood glucose meter, choose **On** or **Off**, then press **Next**.
2. Use the **Up/Down Controller** buttons to enter the lower limit for your blood glucose (BG) goal, then press **Next**.
3. Enter the upper limit for your BG goal, then press **Next**.

NOTE The lower and upper BG limits are only used when viewing BG History (see Chapter 8, Understanding Your Records).

4. Press **Save** to accept the BG goal.

NOTE Check with your healthcare provider before adjusting these settings.

Set the suggested bolus calculator

1. To set the *suggested bolus calculator* feature, choose **On** or **Off**, then press **Next**.

NOTE If the suggested bolus calculator is set to **On**, perform the following steps. If set to **Off**, you will be prompted to "Select bolus increment" and "Enter maximum bolus."

Enter target blood glucose value

1. Use the **Up/Down Controller** buttons to enter a *target blood glucose* (BG) value, then press **Next**.
2. Use the **Up/Down Controller** buttons to enter the "correct above" value or *correction threshold* (the BG value above which you want the PDM to suggest a *correction bolus*), then press **Next**.

NOTE If the suggested bolus calculator is **On**, a correction bolus will be suggested only when your BG is above the value shown in brackets on the screen.

3. To save the target BG value, press **Done**. To change these settings, select the segment you wish to change and press **Edit**.

   You can define up to 4 target BG time segments. To enter additional segments, choose **[add new]**, then:

   a. Press **New**.
   b. Enter a start time for the target BG segment, then press **Enter**.
   c. Enter an end time for the target BG segment, then press **Next**.
   d. Enter a target blood glucose value, then press **Next**.

e. Use the **Up/Down Controller** buttons to enter the "correct above" value or correction threshold (the BG value above which you want the PDM to suggest a correction bolus), then press **Next**.

f. When you have finished entering segments, press **Done**.

4. To see the segments as a list, press **List**. To return to the graphic view, press **Graph**.
5. Press **Save** to accept the target BG profile you have set.

Enter minimum BG allowed for use in bolus calculation

1. Use the **Up/Down Controller** buttons to enter a minimum blood glucose value, below which the System will not calculate a suggested bolus. The values are in 0.1 mmol/L increments and range from 2.8 to 3.9 mmol/L.
2. Press **Next**.

Enter insulin-to-carbohydrate ratio

1. Use the **Up/Down Controller** buttons to enter your *insulin-to-carbohydrate ratio*, then press **Next**. (Insulin-to-carbohydrate ratio is the number of carbs covered by 1 unit of insulin.)
2. To save the ratio, press **Done**. To change the ratio, select the segment you wish to change and press **Edit**.

   You can define up to 4 insulin-to-carbohydrate time segments. To enter additional ratios, choose **[add new]**, then:

   a. Press **New**.

   b. Enter a start time for the segment, then press **Next**.

   c. Enter an end time for the segment, then press **Next**.

   d. Enter the insulin-to-carb ratio for the new time segment, then press **Next**.

   e. To save the new ratio, press **Done**.
3. To see the ratios as a list, press **List**. To return to the graphic view, press **Graph**.
4. Press **Save** to accept the ratios you have set.

Enter correction factor

1. Use the **Up/Down Controller** buttons to enter how much one unit of insulin decreases your blood glucose, then press **Next**.
2. To save the *correction factor*, press **Done**. To change the factor, select the segment you wish to change and press **Edit**.

You can define correction factors for up to 4 time segments. To enter additional correction factors, choose **[add new]**, then:

a. Press **New**.
b. Enter a start time for the segment, then press **Next**.
c. Enter an end time for the segment, then press **Next**.
d. Enter the correction factor, then press **Next**.
e. To save the new correction factor segment, press **Done**.

3. To see the factors as a list, press **List**. To return to the graphic view, press **Graph**.
4. Press **Save** to accept the correction factors you have set.

Set reverse correction

1. To set reverse correction, use the **Up/Down Controller** buttons to choose **On** or **Off**, then press **Next**.

If you enter carbs and reverse corrections are **On**, the System will subtract insulin from the suggested meal bolus to compensate for a low blood glucose (below the BG target you set). With reverse correction **Off**, the System will not subtract insulin from the suggested meal bolus dose due to a low BG. Follow your healthcare provider's recommendation to set reverse correction **On** or **Off**.

Enter the duration of insulin action

1. Use the **Up/Down Controller** buttons to enter the *duration of insulin action* (how long insulin lasts in your body), then press **Next**.

The duration-of-insulin-action setting is used to calculate the amount of insulin on board (IOB) from a previous correction bolus or meal bolus, when you use the suggested bolus calculator.

Select bolus increment and enter maximum bolus

1. Choose a bolus increment (how much each press of the **Up/Down Controller** buttons will increase or decrease a bolus amount)—either 0.05, 0.10, 0.50, or 1.00 units of insulin—then press **Next**.
2. Choose the maximum bolus you can give at one time, then press **Next**.

The maximum bolus default is 10 units. Check with your healthcare provider before adjusting these settings.

Set extended bolus doses

1. To set the units for an extended bolus dose, choose **%** for percent of the total bolus, or choose **Units** for units of insulin. To turn off the extended bolus feature, choose **Off**. Then press **Next**.

Set low reservoir advisory

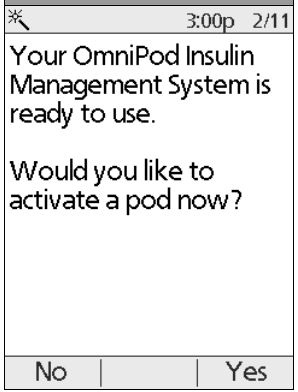
1. Choose the level of insulin in the reservoir at which the PDM should give you an alarm. Choose from 10 to 50 units in 5-unit increments, then press **Next**.

Set expiration notification

1. Choose the number of hours before a Pod expires when the PDM should give you a notification, then press **Next**. The values are in 1 hour increments and range from 1 to 24 hours. (The default is 4 hours.)

   The PDM now asks whether you want to activate a Pod (Figure 2-4).

Figure 2-4



- Press **Yes** if you are ready to activate a new Pod. See Chapter 5, Using the Pod, to learn how to activate a new Pod.
- Press **No** if you do not want to activate a Pod at this time. The PDM displays the **Home** screen.

NOTE You can press and hold the **Power** button to turn off the PDM at any time during setup. Otherwise, it turns off automatically after 5 minutes. If you do not complete the entire setup within 60 minutes, when you turn on the PDM again you will return to the beginning of the Setup Wizard.

Your healthcare provider will help you fill and apply your first Pod. The process is easy because on-screen messages walk you through every step. Please refer to Chapter 5, Using the Pod, for detailed instructions.

TIP You may want to adjust the PDM screen time-out and backlight time-out. For more information on how to do this, see Chapter 6, Using the Personal Diabetes Manager.

TIP Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset your PDM, having these settings handy will make setup very easy. The data management software will also retain your settings.

CHAPTER 3

Understanding and Adjusting Basal Rates

What Is a Basal Rate?

A basal rate is a small base or background amount of insulin that is delivered, at a preset rate, continuously for a specified period of time.

Even without eating, our bodies need a small, constant supply of insulin for normal daily living. In people without diabetes, the pancreas continuously delivers this basal insulin. For people using the OmniPod Insulin Management System, the Pod mimics a healthy pancreas by delivering insulin at the rate that you've programmed into the Personal Diabetes Manager (PDM).

NOTE

Approximately 50% of a person's total daily insulin dose typically comes from basal insulin delivery; the remaining 50% typically comes from bolus doses (see Chapter 4, Understanding and Delivering Bolus Doses).

Personalized Basal Programs

Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver slightly more or less insulin at certain times. For example, one person may need to deliver a higher rate of insulin during the early morning and a lower rate during the late evening. A basal program describes the amount of insulin to be delivered during an entire 24-hour period.

A basal program contains at least one basal rate for the 24-hour period, but for most people it will be broken into several time segments, or basal segments, each delivering a different rate of insulin. A sample basal program with three basal segments might be:

12:00 am–8:00 am	0.60U/hr	Between 12:00 am (midnight) and 8:00 am, the Pod delivers 0.60 units of insulin per hour.
8:00 am–3:00 pm	0.80U/hr	Between 8:00 am and 3:00 pm, the Pod delivers 0.80 units of insulin per hour.
3:00 pm–12:00 am	0.70U/hr	Between 3:00 pm and 12:00 am (midnight), the Pod delivers 0.70 units of insulin per hour.

In addition to normal daily changes, insulin needs can vary with different routines or days of the week. For example, regular school or workday routines may differ from weekend routines, and insulin needs may differ, too. With your healthcare provider, you will decide on the basal rates that best match your lifestyle and insulin needs. You will enter at least one basal program (your Basal 1 program) into your PDM during the setup process (see Chapter 2, Getting Started). You can add other programs later as you fine-tune your System settings or when your needs change.

You can also create temporary basal presets to use on occasions when you need to adjust your basal rate for a short period of time. See "Temporary Basal Rates and Presets" later in this chapter.

Create a basal program

The Personal Diabetes Manager can store up to 7 different basal programs. Each program can contain 24 rates, programmed in half-hour increments. Once you enter a basal program into the PDM, you only need to press a few buttons to pick the program you want. The Pod continues to deliver insulin at those rates until you change that program or switch to another one.

NOTE Check with your healthcare provider before adjusting these settings.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs** (Figure 3-1), then press **Select**.

Figure 3-1

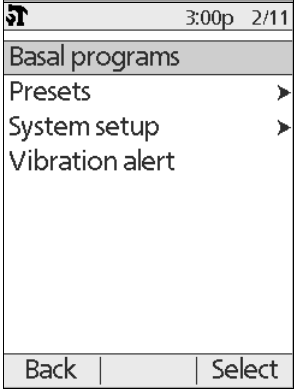
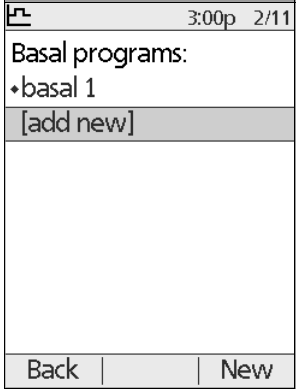


Figure 3-2



3. Choose **[add new]** (Figure 3-2), then press **New**.
4. To use the default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as basal 1, basal 2, basal 3.

   If you want to give a different name to the program:

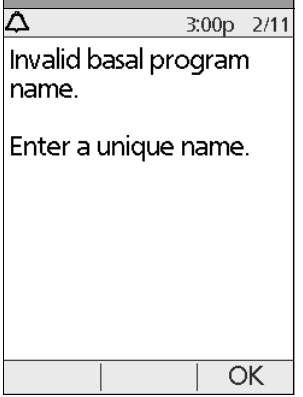
   a. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down-arrow symbol on the screen indicates the character you are changing.

b. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character.

c. Enter each character one at a time. For example, if your weekend schedule is different from your weekday schedule, you might enter W, e, e, k, e, n, d (Figure 3-3). (A blank character or space is the first and last option in the scrolling menu.)

Figure 3-3

Figure 3-4



d. Press **Next**.

NOTE

As a safety feature, the words "Invalid basal program name" (Figure 3-4) appear if the name you entered does not have at least one character or if the name is being used for another basal program. Capitals and lowercase letters are considered the same. Press **OK** to return to the previous screen and enter a different name.

5. Enter the rate, in U/hr, for the first basal segment (from 0.05 to the maximum you entered during setup), then press **Next**.
6. Review the list showing your new basal program.

   To use the same basal rate for the entire 24-hour program, press **Done** and continue with step 7.

   Or, to add basal segments and rates (for example, a higher basal rate between 8:00 am and 3:00 pm):

   a. Choose an existing basal segment, then press **Edit**.

      Or, choose **[add new]**, then press **New**.

   b. Enter the start time (for example, 8:00 am), then press **Next**. Basal segments are in 30-minute increments.

   c. Enter the end time (for example, 3:00 pm), then press **Next**.

   d. Enter the rate for the new basal segment (for example, 0.80U/hr), then press **Next**.

NOTE Basal rates outside the changed segment do not change.

e. Repeat steps a–d for each new segment and rate you want, then press **Done**.

NOTE Press and hold the **Power** button to turn the screen back on. In some cases, if it has been less than 5 minutes since the screen timed out, pressing the **Power** button returns you to the same screen you were using. If it has been longer than 5 minutes, the PDM brings you to the **Status** screen.

7. Review the graph of the new basal program (Figure 3-5).
8. To see the program as a list, press **List** (Figure 3-6). To see the graph again, press **Graph**.

   The total daily basal that will be delivered is shown at the bottom of each "Basal programs" graph and list.
9. To add the program to the PDM's memory, press **Save**.

Repeat steps 1 through 9 above for each basal program (up to 7) you want to create.

Figure 3-5

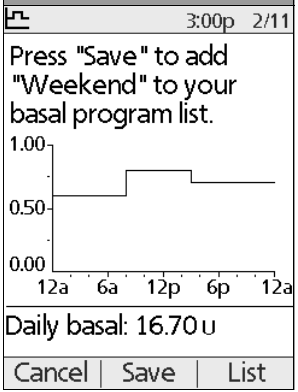


Figure 3-6

3:00p 2/11
Press "Save" to add "Weekend" to your basal program list.
Segment U/hr
12:00a - 8:00a 0.60
8:00a - 3:00p 0.80
3:00p - 12:00a 0.70
Daily basal: 16.70 U
Cancel | Save | Graph

Enable an existing basal program

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs**, then press **Select**.

3. Choose the program you want from the list (Figure 3-7), then press **Enable**.

Figure 3-7

NOTE A diamond icon (♦) appears next to the program that is active. You cannot select the active program to enable it, because it is already running.

4. Press **Enable** again to start the selected basal program. If a Pod is active, the PDM beeps to indicate that the chosen basal program is running.

NOTE As a safety feature, you cannot enable a new basal program while a temporary basal program is in process (see "Temporary Basal Rates and Presets" later in this chapter); you must first cancel the active temporary basal program.

Change, rename, copy, or delete a basal program

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs**, then press **Select**.
3. Choose a program from the list, then press **Select**.

To view the segments of the basal program

1. Choose **View**, then press **Select** (Figure 3-8).

Figure 3-8

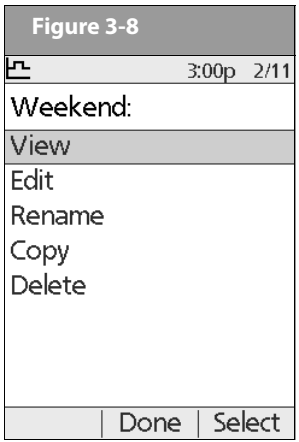
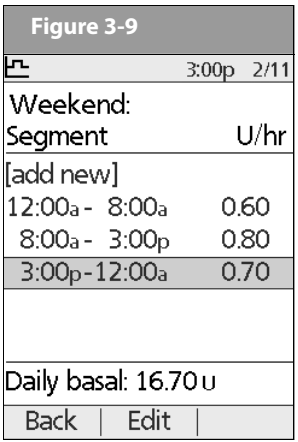


Figure 3-9



To edit or add a segment or rate in the basal program

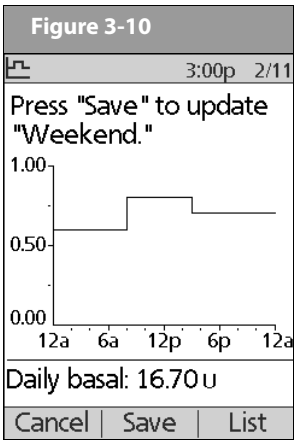
1. Choose **Edit**, then press **Select**.

NOTE

As a safety feature, you must suspend insulin delivery before editing an active basal program (see Chapter 5, Using the Pod.) Remember to resume delivery after the edits are made.

2. Choose the segment to change, then press **Edit** (Figure 3-9). Or, choose **[add new]**, then press **New**.
3. Enter a start time for the segment you want to change, then press **Next**.
4. Enter an end time for this segment, then press **Next**.
5. Enter a basal rate for the new segment, then press **Enter**.
6. To save the newly entered segment into the basal program, press **Save** (Figure 3-10). If you want to make additional edits, repeat steps 2–5.

Figure 3-10



7. To see the program as a list, press **List**. To see the graph again, press **Graph**.

To rename a basal program

1. After choosing a program from the list, choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the new name you want. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character, then press **Save**.

To copy a basal program

1. After choosing a program from the list, choose **Copy**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want for the copied file. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character, then press **Next**.
3. To use the same basal program for the entire 24-hour period, press **Save**.

To edit or add segments to the newly copied basal program, follow the steps under "To edit or add a segment or rate in the basal program" earlier in this chapter.

Instead of suspending, changing, and then resuming the active basal program, try this: Copy the active program, rename it, make the changes, save it, then enable it.

To delete a basal program

1. After choosing a program from the list, choose **Delete** and then press **Select**.
2. Press **Delete** to permanently delete the program.

As a safety feature, you cannot delete the active basal program.

Temporary Basal Rates and Presets

What is a temporary basal rate?

A temporary basal rate lets you adjust your basal rate for a predetermined period of time.

On occasion, you may need to change the active basal rate for only a short time. For example, if you are going cross-country skiing for several hours, you may want to lower the basal rate during and after you exercise. This is called a "one-time temporary basal rate."

Some temporary changes are easy to predict and respond to. They happen routinely and you may know from experience how they affect your insulin needs. For example, you might take the same exercise class twice a week for a few weeks or months, or

join a summer soccer league. For women, a monthly hormonal change that affects blood glucose is an example of predictable change. To easily handle predictable, short-term changes, you can "preset" a temporary basal rate, so it is ready whenever you need it. The PDM can remember up to 7 temporary basal presets.

You can set a temporary basal rate for a duration of 30 minutes to 12 hours. Once the time limit is reached, the PDM automatically returns to the active basal program.

When using units per hour, the OmniPod System allows you to set temporary basal rates from 0.0 U/hr, up to your max basal rate. When using percent rate, you can set temporary basal rates from -100% to +95% of your active rate, as long as the temporary rate is less than or equal to your max basal rate.

See the sections below on creating, enabling, canceling, and changing temporary basal presets.

Enable a one-time temporary basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Temp basal**; then press **Select**.
2. If you have created temp basal presets, choose **[enter manually]** from the list, then press **Select**.

   If you have not created any temp basal presets, the PDM skips this step.
3. Enter the temporary basal rate in either units per hour (Figure 3-11) or percent change (Figure 3-12), depending on how you chose to show the rates; then press **Enter**.

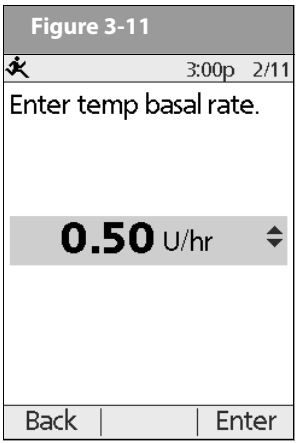


Figure 3-11

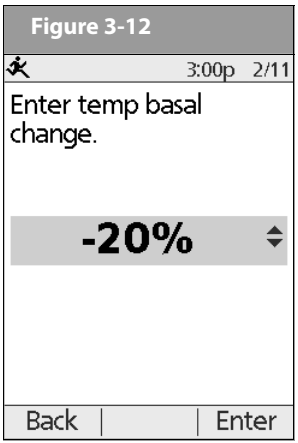


Figure 3-12

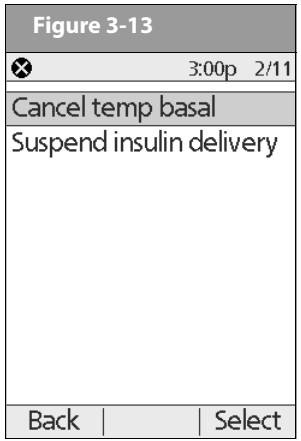
NOTE During initial setup, you and your healthcare provider either turned **Off** temporary basal rates or chose to show the rates as **%** or **U/hr**. To change this setting, see Chapter 6, Using the Personal Diabetes Manager.

4. Enter the duration for the temporary rate, then press **Enter**.
5. Press **Confirm** to start the temporary basal rate shown on the screen. The Pod beeps to indicate that the temporary basal rate is running.

Cancel a one-time temporary basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend/cancel**; then press **Select**.
2. Choose **Cancel temp basal** (Figure 3-13), then press **Select**.

Figure 3-13



3. Press **Confirm** to cancel the temporary basal shown on the screen.

Create a temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Temp basal presets**, then press **Select**.
4. Choose **[add new]**, then press **New**.
5. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as temp basal 1, temp basal 2, temp basal 3.

   Or, to give a different name to the program:

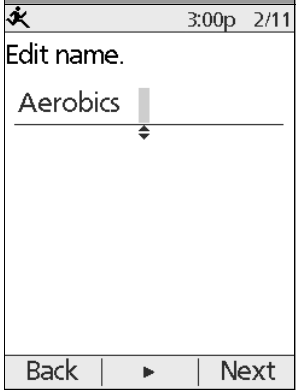
   a. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down-arrow symbol on the screen indicates the character you are changing.

   b. Press the middle soft key to move the underscore to the next character.

   c. Enter each character one at a time. For example, if you take an aerobics class two nights a week, you might enter A, e, r, o, b, i, c, s (Figure 3-14 on the next page). (A blank character or space is the first and last option in the scrolling menu.)

   NOTE Capitals and lowercase letters are considered the same.

Figure 3-14



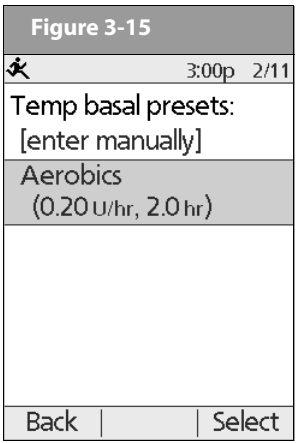
d. Press **Next**.

6. Enter the new temporary basal rate (or percent change), then press **Next**.
7. Enter the duration of the temporary basal rate, from 0.5 hours to 12 hours, then press **Next**.
8. Review the temporary basal name, rate, and duration, then press **Save** to accept it.

Enable an existing temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Temp basal**; then press **Select**.
2. Choose the temporary basal preset you want to use from the list (Figure 3-15), then press **Select**.

Figure 3-15



3. If you want, change the duration for the temporary rate, in half-hour increments, then press **Enter**.
4. Press **Confirm** to begin the temporary basal rate shown on the screen. The Pod beeps to indicate that the chosen temporary basal preset is running.

Cancel an active temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend/cancel**; then press **Select**.
2. Choose **Cancel temp basal**, then press **Select**.
3. Press **Confirm** to cancel the actively running temporary basal preset.

NOTE If you suspend insulin delivery while a temp basal is running, the temp basal will be cancelled when you resume.

Change, rename, or delete a temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Temp basal presets**, then press **Select**.
4. Choose a temporary preset from the list, then press **Edit**.

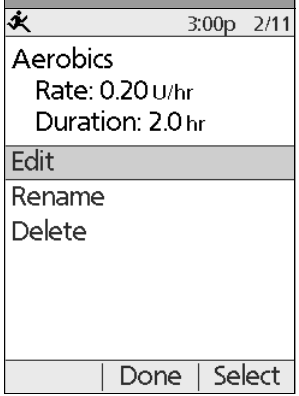
NOTE You cannot edit, change, or delete a temporary basal preset that is actively running.

5. Follow the steps below.

To change a temporary basal preset

1. Choose **Edit**, then press **Select** (Figure 3-16).

Figure 3-16



2. Enter a new rate (or new percent change), for the preset, then press **Next**.
3. Enter a new duration for the preset, then press **Save**.
4. Press **Done.**

To rename a temporary basal preset

1. Choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want; then press **Save**.
3. Press **Done.**

To delete a temporary basal preset

1. Choose **Delete**, then press **Select**.
2. Press **Delete** to permanently delete the preset.

Maximum Basal Rate

What is the maximum basal rate?

The maximum basal rate is a safety feature that limits the basal rate (U/hr) that the Pod can deliver. Once you enter it into the PDM memory, the maximum applies to both regular basal programs and temporary basal rates.

You and your healthcare provider will enter an initial maximum basal rate into your PDM during the setup process (see Chapter 2, Getting Started). You can change it later as you fine-tune your System settings or when your needs change.

Change the maximum basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Bolus/basal/calcs**, then press **Select**.
4. Choose **Max basal**, then press **Select**.
5. Enter a new maximum basal rate, then press **Enter**.

CHAPTER 4

Understanding and Delivering Bolus Doses

What Is a Bolus?

A bolus is an extra dose of *insulin*, delivered when needed to:

- Match the *carbohydrates* (sugar content) in a meal or snack—also known as a meal bolus
- Lower *blood glucose* when it gets too high—also known as a correction bolus

This extra dose is in addition to the *basal rate* delivered throughout the day and night (see Chapter 3, Understanding and Adjusting Basal Rates).

The size of a *bolus dose* depends on the factors current at the time you deliver the bolus:

- Your *blood glucose level*
- Your *insulin-to-carbohydrate ratio*
- Your *correction factor*
- Your target blood glucose
- The amount of *insulin on board (IOB)* from previous meal and correction boluses
- Your *correction threshold,* the BG level above which you would like to take insulin to reduce an elevated blood glucose
- Your activity level
- The type and amount of food you eat

With the OmniPod System, it is easy to adapt to any situation. With just a few button presses, you can adjust to unexpected or changing insulin needs.

During setup, you entered bolus dose settings in the PDM (see Chapter 2, Getting Started). You can adjust these settings as you fine-tune your System or when your needs change (see Chapter 6, Using the Personal Diabetes Manager).

Check with your *healthcare provider* before you adjust these settings.

Bolus Dose Options

So that you can fully enjoy freedom and flexibility in your life, the OmniPod System offers the following bolus dose options:

Suggested bolus calculator: When you want the System to calculate your *suggested bolus*, based on your personal settings, your current blood glucose, the amount of insulin still active in your body from previous boluses, and the grams of carbohydrate ("carbs" for short) you are about to eat

Normal bolus: When you need a dose of insulin right away, to cover a meal or snack you are about to eat or to reduce a high blood glucose level

Extended bolus: When you are eating high-fat or high-protein foods (which take longer to digest and are slower to affect blood glucose) or when you are eating for an extended period (for example, at a party or during a holiday meal)

NOTE

The bolus features in the OmniPod System are designed for flexibility and convenience. You can easily transition from a normal to an extended bolus with just a few button presses.

Suggested Bolus Calculator

The suggested bolus calculator lets the OmniPod System recommend your bolus based on your personal settings. To review or adjust these settings—including turning the suggested bolus calculator **On** or **Off**—see Chapter 6, Using the Personal Diabetes Manager.

If the suggested bolus calculator is turned **On**, the System automatically calculates a bolus dose. If the suggested bolus calculator is turned **Off**, you must enter a bolus amount manually.

WARNING

The suggested bolus calculator will display a suggested bolus dose based on the settings you have programmed into the PDM. Check with your healthcare provider before using this feature or adjusting these settings.

How a suggested bolus is calculated

The suggested bolus calculator estimates the suggested amount for each bolus portion based on your personal settings and inputs.

The settings used to calculate a suggested bolus are:

- target BG
- insulin-to-carbohydrate (IC) ratio
- correction factor (CF)
- duration of insulin action

The inputs used to calculate a suggested bolus are:

- current BG
- carbs entered
- insulin on board (IOB)

A suggested bolus can have a correction bolus only, a meal bolus only, or both.

Correction bolus: The correction bolus, as the name suggests, "corrects" for a blood glucose (BG) level above your target BG level.

Meal bolus: The meal bolus provides insulin for the carbohydrates you enter into the System.

Insulin on board (IOB): IOB is the amount of insulin still working in your body from previous boluses. The amount of time insulin remains "on board" or "active" depends on what you set for your duration of insulin action.

NOTE The OmniPod System can only subtract insulin on board (IOB) from a suggested bolus when the current BG is known.

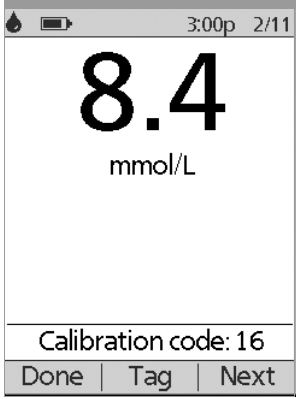
For formulas for each element of the suggested bolus calculation, detailed examples, and additional guidelines of how the suggested bolus calculator works, see the Appendix.

Deliver a Normal Bolus

Deliver a bolus when suggested bolus calculator is On

1. After you check your blood glucose, the PDM displays the results (Figure 4-1; see the end of Chapter 7, Checking Your Blood Glucose). Press **Next**.

Figure 4-1



NOTE A blood glucose value is current for up to 10 minutes after it is tested. So you can wait up to 10 minutes, restart the *bolus* process, and not have to retest your blood glucose in order to include it in the suggested bolus calculator.

NOTE When your blood glucose result reads "HIGH" or "LOW," the suggested bolus calculator will be disabled.

NOTE If you use a separate blood glucose meter—not the Personal Diabetes Manager (PDM)—you will need to enter your blood glucose manually. On the **Home** screen, choose **Bolus**, then press **Select**. Use the **Up/Down Controller** buttons to enter your current BG value, then press **Yes** if you want this value to be used by the suggested bolus calculator.

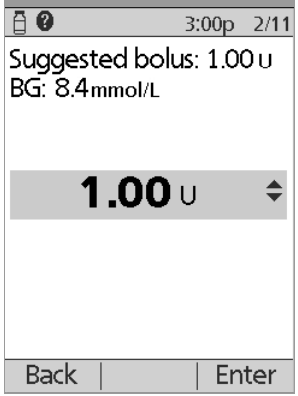
NOTE You can also enter a BG manually by choosing the **More actions** menu, then choosing **Add BG Reading**. See the end of Chapter 7, Checking Your Blood Glucose.

2. If you are <u>not</u> going to eat now, press **No** (Figure 4-2). The Suggested Bolus screen appears (Figure 4-3). Press **Enter** to accept the suggested bolus.

   Or, if you wish, press the **Up/Down Controller** buttons to increase or decrease the suggested bolus. Then press **Enter** to accept the bolus.

Figure 4-2

Figure 4-3



NOTE In the **Suggested Bolus** screen, "adjusted for IOB" appears only when IOB is a factor in the calculation.

TIP To view detailed information about the calculations used for this suggested bolus, press the **User Info/Support** button and scroll through the information screens. Press **Close** to return to the **Suggested Bolus** screen.

3. If you <u>are</u> going to eat now:
   a. Press **Yes** (Figure 4-2 on previous page), enter the number of carbohydrates you are about to eat, then press **Enter**.

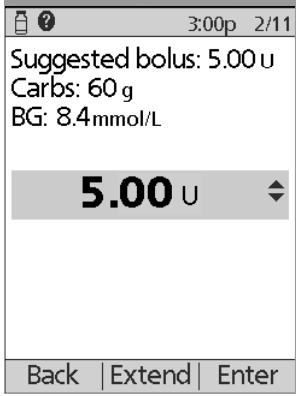
      If you've previously entered a carb preset, then either:

      - Use the **Up/Down Controller** buttons to choose **[enter manually]**, then press **Select**. Enter the number of carbohydrates that you are going to eat, then press **Enter**.
      - Use the **Up/Down Controller** buttons to choose favorites, snacks, or meals. From there, select a carb preset you have previously entered (see "Carb Presets" later in this chapter), then press **Select**.

   b. Press **Enter** to accept the suggested bolus (Figure 4-4).

      Or press the **User Info/Support** button to view calculation information used for this suggested bolus. Press **Close** to return to the **Suggested Bolus** screen, then press **Enter**.

Figure 4-4



NOTE If the *reverse correction* feature is turned **On** and if your blood glucose level is below your target, the System subtracts a correction amount from the meal portion of the bolus.

NOTE If the reverse correction setting is turned **Off**, the System does not subtract anything for a blood glucose level below your target.

4. If you have set the blood glucose reminder option to **On** and you want to add a reminder:
   a. Press **Yes**.
   b. Enter the time for the reminder, then press **OK**.
5. Press **Confirm** to begin the bolus delivery.

Deliver a bolus manually (suggested bolus calc is Off)

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Bolus**; then press **Select**.
2. Enter the number of units you want to deliver, then press **Enter**.
3. If the blood glucose reminders feature is turned **On**, you can now set a blood glucose reminder.
4. Press **Confirm** to begin the bolus delivery.

NOTE

As a safety feature, the OmniPod System only allows you to give a bolus at or below the maximum bolus dose you have set. See Chapter 6, Using the Personal Diabetes Manager, for information on resetting your maximum bolus dose. Consult your healthcare provider before changing this setting.

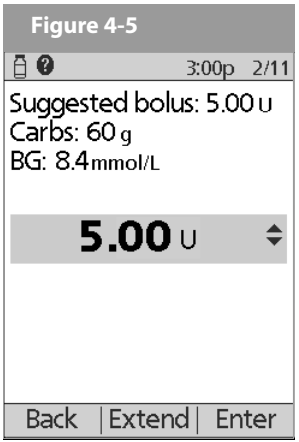
Deliver an Extended Bolus

The extended bolus feature lets the OmniPod System deliver some (or no) insulin now and the remainder over a period of time you choose.

Deliver an extended bolus instead of a normal bolus

1. After you get your suggested bolus, press **Extend** instead of **Enter** (see Figure 4-5).

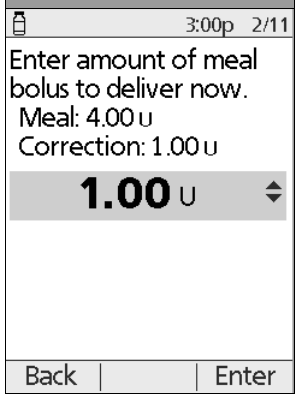
Figure 4-5



NOTE If you have set the Extended bolus option to **Off**, the PDM will not display the **Extend** soft key. For information on turning this feature on and off, see Chapter 6, Using the Personal Diabetes Manager.

2. Enter the units of insulin or percentage of the bolus that you want to take immediately (Figure 4-6), then press **Enter**.

Figure 4-6



NOTE To learn how to set extended boluses in percentages or units, see Chapter 6, Using the Personal Diabetes Manager.

3. Enter the time (up to 8 hours, in 30-minute increments) over which to deliver the remainder of the bolus, then press **Enter** (Figure 4-7). In Figure 4-8 you can see a detail of the extended bolus.

Figure 4-7

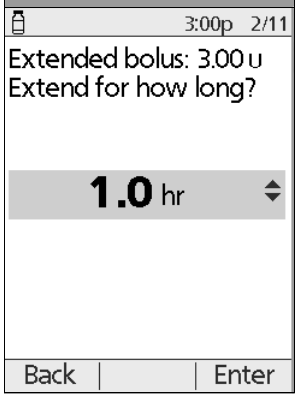
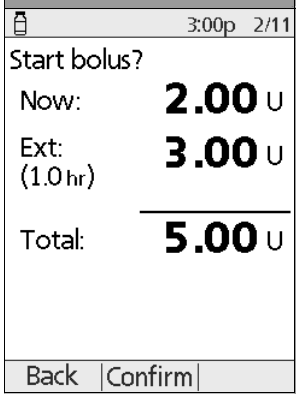


Figure 4-8



4. If the blood glucose reminders feature is turned **On**, you can now set a blood glucose reminder.
5. Press **Confirm** to begin the bolus delivery.

NOTE As a safety feature, the correction bolus is always delivered first and cannot be extended. Only the meal bolus can be extended. For example:

Total bolus = 5 units
- *Correction bolus* — *1 unit*
- *Meal bolus* — *4 units*

Deliver now = 2 units
- *100% of correction bolus* — *1 unit*
- *25% of meal bolus* — *1 unit*

Extend = 3 units
- *75% of meal portion* — *3 units*

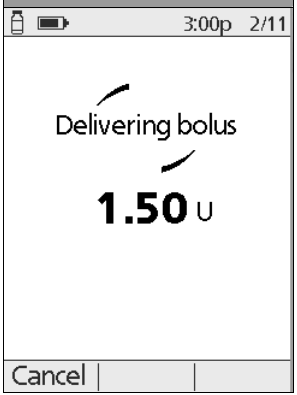
NOTE As a safety feature, you cannot deliver two extended boluses at the same time. You can, however, cancel the first extended bolus and replace it with another (see "Replace an Extended Bolus" on page 36). And you can deliver a normal bolus while an extended bolus is being delivered.

Cancel Active Boluses

The OmniPod System is extremely flexible, so you can use it to respond to your changing insulin needs. It is easy to cancel an active bolus (one that is currently being delivered), even after insulin delivery has started.

1. Press and hold the **Power** button to turn on the PDM, if it is not already on. An on-screen message appears as long as a normal bolus is being delivered (Figure 4-9).

Figure 4-9

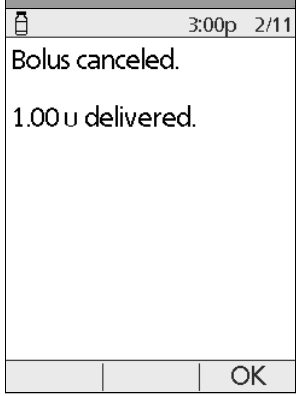


NOTE If the bolus has already been completely delivered, the "Delivering bolus" message and **Cancel** do not appear, but the Status screen does appear.

2. Press **Cancel**.

   The Pod beeps to confirm the bolus is canceled. An on-screen message tells you how much insulin was delivered before you canceled the bolus (Figure 4-10).

Figure 4-10



3. Press **OK** to return to the **Status** screen.

NOTE If your suggested bolus contains both a correction bolus and a meal bolus, the correction bolus is always delivered first.

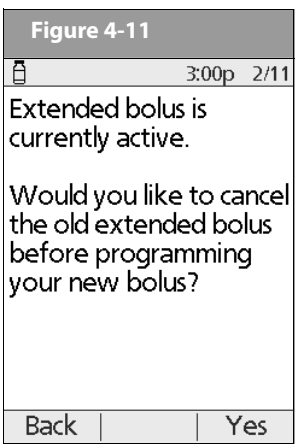
Replace an Extended Bolus

You can replace one extended bolus with another. The System tells you how much of the first bolus has not yet been delivered.

1. After you see your suggested bolus, press **Extend** instead of **Enter** (see Figure 4-5 on page 33).
2. Press **Yes** to cancel the active extended bolus (Figure 4-11).

   Or press **Back** to return to the Suggested Meal Bolus screen.

Figure 4-11


3:00p 2/11
Extended bolus is currently active.
Would you like to cancel the old extended bolus before programming your new bolus?
Back
Yes

3. Press **Confirm** (Figure 4-12).

Figure 4-12

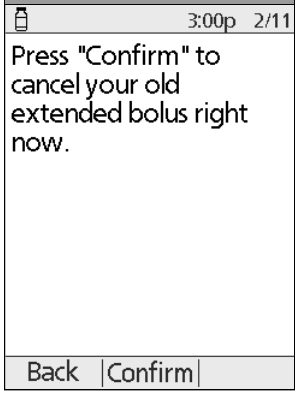
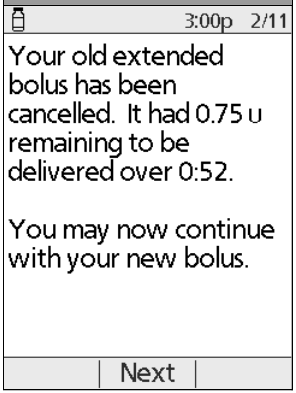


Figure 4-13


3:00p 2/11
Your old extended bolus has been cancelled. It had 0.75 u remaining to be delivered over 0:52.
You may now continue with your new bolus.
Next

4. The screen displays the amount of the old extended bolus that remained to be delivered (Figure 4-13). Press **Next** to return to the Suggested Meal Bolus screen.

TIP You can add what remained of the old extended bolus to the new one.

Bolus Presets

Bolus presets are bolus amounts that you program for frequent use. For example, if you often take the same bolus at lunchtime, you can create a bolus preset for that amount and name it "Lunch."

NOTE Bolus presets are available only when the suggested bolus calculator feature is turned **Off**. (If the suggested bolus calculator is turned **On**, you can still use carb presets. See "Carb Presets" on page 39.)

Create a bolus preset

1. On the **Home** screen use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Bolus presets**, then press **Select**.
4. Choose **[add new]**, then press **New**.
5. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as bolus 1, bolus 2, bolus 3.

Or, to give a different name to the program:

a. Press the **Up/Down Controller** buttons to enter the characters that spell the name you want. An up- and down-arrow symbol on the screen indicates which character you are changing.

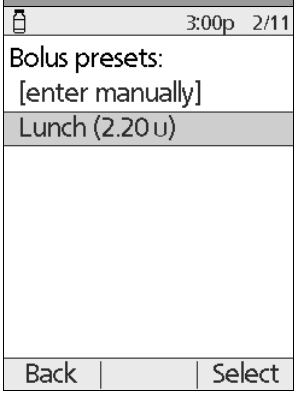
b. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character.

c. Enter each character one at a time. For example, if you frequently take the same bolus at lunchtime, you might enter L, u, n, c, h (Figure 4-14).

d. Press **Next**.

Figure 4-14

Figure 4-15



6. Enter the new bolus preset amount, up to the maximum bolus you entered during setup; then press **Next**.
7. Review the bolus preset name and amount; press **Save** to accept it.

Enable an existing bolus preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Bolus**; then press **Select**.
2. Choose the bolus preset you want to use from the list (Figure 4-15), then press **Select**.
3. Press **Enter** to confirm the bolus preset amount, or, if necessary, use the **Up/Down Controller** buttons to adjust the bolus amount.
4. Press **Confirm** to deliver the bolus shown on the screen.

Change, rename, or delete a bolus preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Bolus presets**, then press **Select**.
4. Choose a preset from the list, then press **Edit**.

Change a bolus preset

1. Choose **Edit**, then press **Select**.
2. Enter a new insulin amount for the bolus, then press **Save**.

Rename a bolus preset

1. Choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want; then press **Next**.

Delete a bolus preset

1. Choose **Delete** and then press **Select**.
2. Press **Delete** to permanently delete the preset.

Cancel an active bolus preset

1. Press and hold the **Power** button to turn on the PDM, if it is not already on. An on-screen message appears as long as a bolus is being delivered.
2. Press **Cancel**.

   The Pod beeps to confirm the bolus is canceled. An on-screen message tells you how much insulin was delivered before you canceled the bolus.
3. Press **OK** to return to the **Status** screen.

For more details, see "Cancel Active Boluses" earlier in this chapter.

Carb Presets

Carb presets are favorite food items, snacks, or meals that you eat frequently. After you enter these items, you can quickly select one when entering carbs during the suggested bolus calculator process.

Create a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category for this carb preset: **Favorites**, **Snacks**, or **Meals**, then press **Select**.
5. Choose **[add new]**, then press **New**.
6. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as carb preset 1, carb preset 2, carb preset 3.

   Or, to give a different name to the program:

   a. Press the **Up/Down Controller** buttons to enter the characters that spell the name you want. An up-and-down-arrow symbol on the screen indicates the character you are changing.

b. Press the middle soft key (the right arrow) to move the underscore to the next character.

c. Enter each character one at a time. For example, if you frequently eat a breakfast of plain low-fat yogurt with blueberries, sweetener, and cinnamon, you might enter B, l, u, e, [space], Y, o, g, u, r, t (Figure 4-16).

Figure 4-16

Figure 4-17

d. Press **Next**.

7. Enter the grams of carbohydrate in the meal, then press **Next**.
8. If you want, enter the grams of fiber, fat, and protein in the meal, and the total calories. Press **Next** after each entry.

NOTE These additional units are not required. If you prefer not to enter them, simply press **Next** repeatedly to step through the screens.

NOTE If you do include grams of fiber in step 8 above, the suggested bolus calculator uses carbs minus fiber. Alternatively, in step 7, you can enter the total of carbs minus fiber yourself. Your healthcare provider can best advise you how to make this entry.

9. Press **Save** to add the preset to the category.

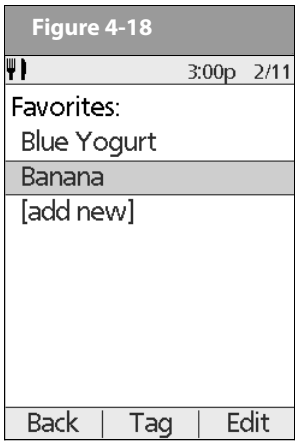
Change or edit a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category of the preset you want to change, then press **Select** (Figure 4-17).

To change the category for a carb preset

1. Choose the carb preset you want to move to another category, then press **Tag** (Figure 4-18).

Figure 4-18



2. Choose a new category, then press **Select**.

To edit a carb preset

1. Choose the carb preset you want to change, then press **Edit**.
2. Press **Edit** again on the next screen.
3. To rename the carb preset, press the **Up/Down Controller** buttons to enter the characters that spell out the name you want, then press **Next**.

   To "erase" characters, press either **Up** or **Down** until you reach the end of the characters, which is a blank.
4. Enter the grams of carbohydrate in the meal, then press **Next**.
5. If you want, enter the grams of fiber, fat, and protein in the meal, and the total calories. Press **Next** after each entry.

   NOTE These additional units are not required. If you prefer not to enter them, simply press **Next** repeatedly to step through the screens.
6. Press **Save** to update the preset.

Delete a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category of the preset you want to change, then press **Select**.
5. Choose the carb preset you want to delete, then press **Edit**.
6. Press **Delete**.
7. Press **Delete** again to permanently delete the preset.

CHAPTER 5

Using the Pod

The Pod Change Process

Refer to the insulin labeling and follow your *healthcare provider*'s directions for how often to replace the Pod. If you like, you can set the PDM to notify you when it is time to replace the Pod (see Chapter 6, Using the Personal Diabetes Manager).

WARNINGS!

- Do NOT apply or use a Pod if its sterile packaging is open or damaged, as this may increase the risk of infection. Pods are sterile unless packaging has been opened or damaged.
- Do NOT apply or use a Pod if it is damaged in any way. A damaged Pod may not work properly.
- To minimize the possibility of site infection, do NOT apply a Pod without first using *aseptic technique*. This means to:
  - Wash your hands.
  - Clean the insulin vial with an alcohol prep swab.
  - Clean the infusion site with soap and water.
  - Keep sterile materials away from any possible germs.
- Do NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives or have fragile or easily damaged skin.
- Check often to make sure the Pod and soft *cannula* are securely attached and in place. A loose or dislodged cannula may interrupt *insulin* delivery.
- Do NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that has not been deactivated properly may continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia.
- Because insulin Pods use only rapid-acting insulin, users are at increased risk for developing *hyperglycemia* (high *blood glucose*) if insulin delivery is interrupted. If it is untreated, severe hyperglycemia can quickly lead to *diabetic ketoacidosis (DKA)*. DKA can cause symptoms like breathing difficulties, shock, coma, or death. If insulin delivery is interrupted for any reason, youmay need to replace the missing insulin—usually with an injection of rapid-acting insulin. Ask your healthcare

provider for instructions on handling interrupted insulin delivery.

Gather equipment and supplies

Gather the following before you begin:

- Vial of rapid-acting U-100 insulin (See the warning on page iv of the Introduction for insulins approved for use in the OmniPod System.)

WARNING

NEVER use insulin that is cloudy; it may be old or inactive. Failure to use rapid-acting U-100 insulin, or using insulin that is expired or inactive, may lead to hyperglycemia or diabetic ketoacidosis (DKA).

- An unopened Pod
- Alcohol prep swab

WARNING

If you are a first-time OmniPod System user, your healthcare provider will guide you through the steps for initializing and applying your first Pod. Do NOT attempt to apply or use a Pod until you have been trained by your healthcare provider. Use of the System with inadequate training or improper setup could put your health and safety at risk.

Deactivate the current Pod

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**, then press **Select**.
2. Choose **Change Pod** (Figure 5-1), then press **Select**.
3. Press **Confirm** (Figure 5-2) to deactivate the current Pod.

Figure 5-1

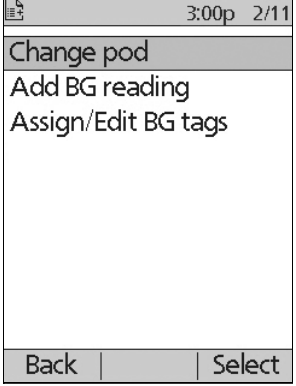
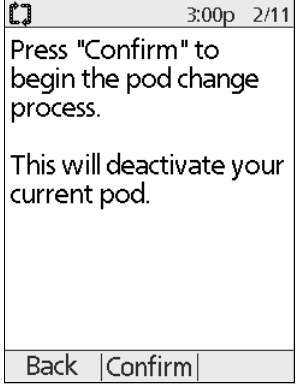


Figure 5-2



4. If an extended bolus or temporary basal or both are actively running, you will see the message in Figure 5-3. Press **Confirm** to accept the cancellation.

   Or press **Back** to return to the **More actions** menu.

Figure 5-3

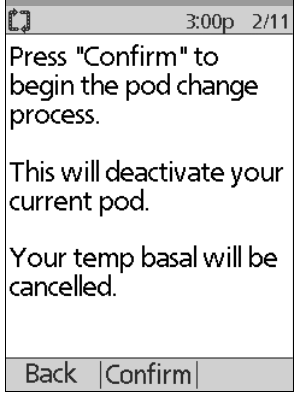

3:00p 2/11
Press "Confirm" to begin the pod change process.
This will deactivate your current pod.
Your temp basal will be cancelled.
Back
Confirm

Figure 5-4

5. After you press **Confirm**, you will see the message in Figure 5-4. To remove the old Pod:
   a. Gently lift the edges of the adhesive tape from your skin and remove the entire Pod (Figure 5-5).

TIP Removing the Pod slowly will help to avoid possible skin irritation.

Figure 5-5

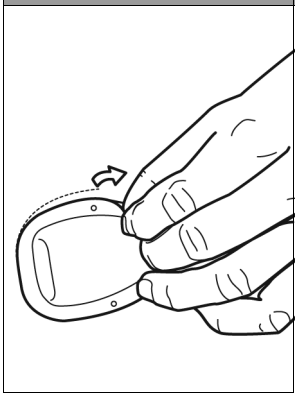
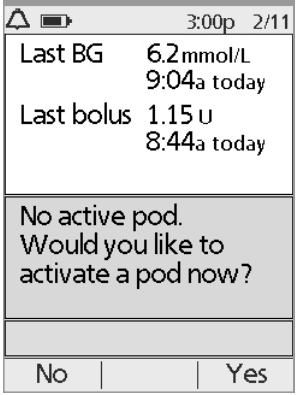


Figure 5-6



   b. Use soap and water to remove any adhesive that remains on the skin or, if necessary, use an adhesive remover.

CAUTION Check the infusion site for signs of infection. See "Avoid Infusion Site Infections" later in this chapter.

   c. Pods contain batteries that must not be disposed of with household waste. To dispose of expired Pods, follow the instructions you receive from the distributor or from Customer Care.

6. After removing the old Pod, press **Next** (Figure 5-4).
7. Press **Yes** to fill a new Pod (Figure 5-6).

Fill a new Pod

CAUTION

Before filling a Pod with insulin, ensure that the Pod is above 10° Celsius (50° Fahrenheit). If the Pod has been exposed to temperatures below 10° C (50° F), then allow the Pod to be brought back to room temperature before filling it with insulin.

1. Use an alcohol prep swab to clean the top of the insulin vial, then discard the prep swab.
2. Securely twist the fill needle onto the syringe (Figure 5-7).

Figure 5-7

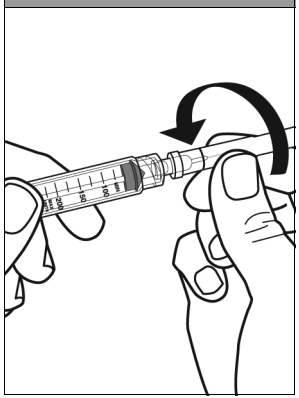
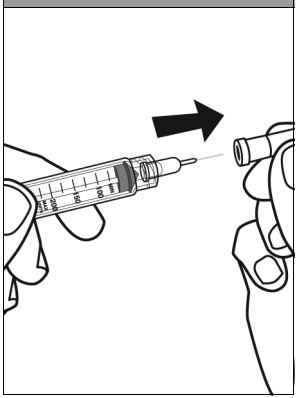


Figure 5-8



3. Pull outward to remove the protective cap from the needle (Figure 5-8). Save the cap; you will need it later.

CAUTION

Use care after removing the needle cap and exposing the fill needle.

CAUTION

Only use room temperature insulin when filling the Pod.

4. Determine the amount of insulin you need to insert into the Pod. For example, if you will use this Pod for 48 hours, you need enough insulin to last you 48 hours. Your healthcare provider will help you determine the correct amount.

NOTE

The Pod requires a minimum of 85 units of insulin to begin operation.

NOTE

The Pod can deliver up to 200 units of insulin.

5. Draw air into the syringe up to the amount of insulin you want.
6. Insert the needle into the insulin vial and inject the air. This makes it easier to withdraw insulin from the vial.

7. Turn the vial and syringe upside down. Withdraw insulin from the vial into the syringe, expelling any air bubbles. Fill at least to the MIN (minimum) fill line (Figure 5-9).

Figure 5-9

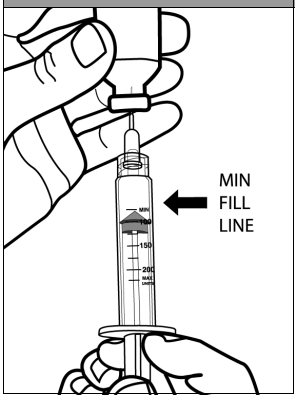
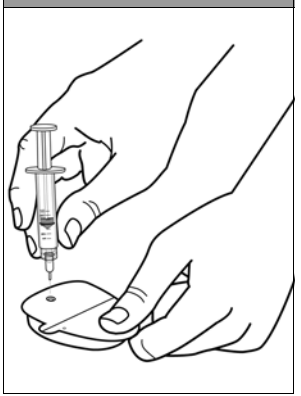


Figure 5-10



CAUTION

Avoid using insulin from more than one vial, which may introduce air into the syringe.

8. Remove the needle from the vial and insert it straight down into the insulin fill port on the underside of the Pod (Figure 5-10).

CAUTION

To ensure proper fill, do not insert fill syringe at an angle into the fill port.

CAUTION

Do not use any other type of needle or filling device besides the syringe provided with each Pod.

9. Depress the syringe plunger to completely empty the insulin into the Pod. The Pod will beep, indicating that the System is ready to proceed to the next step.

WARNING

NEVER use a Pod if you hear a crackling noise or feel resistance when you depress the plunger. These conditions can result in underdelivery of insulin.

10. Remove the needle from the insulin fill port. The port is self-sealing; insulin will not leak after the needle is removed.

CAUTION

Do not insert the fill syringe into the fill port more than once.

WARNING

NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

11. Place the protective cap back on the needle and remove the needle from the syringe.
12. Place the capped needle in a *sharps container*. Dispose of used needles according to local waste disposal regulations.

CAUTION

The fill syringe is intended for single use only and should be used only with the OmniPod System.

13. After you fill the Pod, it will beep twice. After you hear the beeps, press **Next** (Figure 5-11).

    The Pod will only beep if you have filled it with at least 85 units of insulin.

    If you have filled the Pod with more than 85 units and still do not hear the 2 beeps, call Customer Care.
14. The System performs a series of safety checks and automatically primes the Pod (Figure 5-12). Once complete, the PDM beeps, letting you know that the priming and safety checks were successful.

NOTE

After filling the Pod with insulin, you should complete the Pod-change process within 60 minutes. As a reminder that the Pod has been filled, it will beep every 5 minutes to indicate that time is passing. If you do not set up the Pod within 60 minutes, you must deactivate and discard it.

Figure 5-11

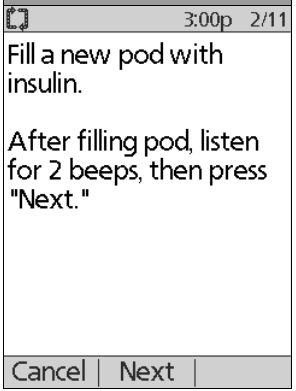
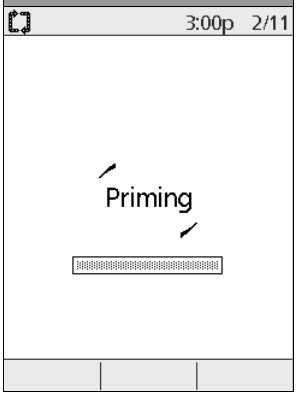


Figure 5-12



NOTE

Once a Pod is activated and communicates with the PDM, it can only receive commands from that PDM, not from any other.

Select the infusion site

Before applying a new Pod, you must first select an appropriate *infusion site*. Due to ease of access and viewing, the abdomen is often used. Your healthcare provider may suggest other potential sites that, like the abdomen, typically have a layer of fatty tissue, such as the hip, back of upper arm, upper thigh, or lower back (Figure 5-13, and Figure 5-14 on the following page).

CAUTION

Avoid sites where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the Pod. Also avoid sites where the Pod will be affected by folds of skin.

CAUTION

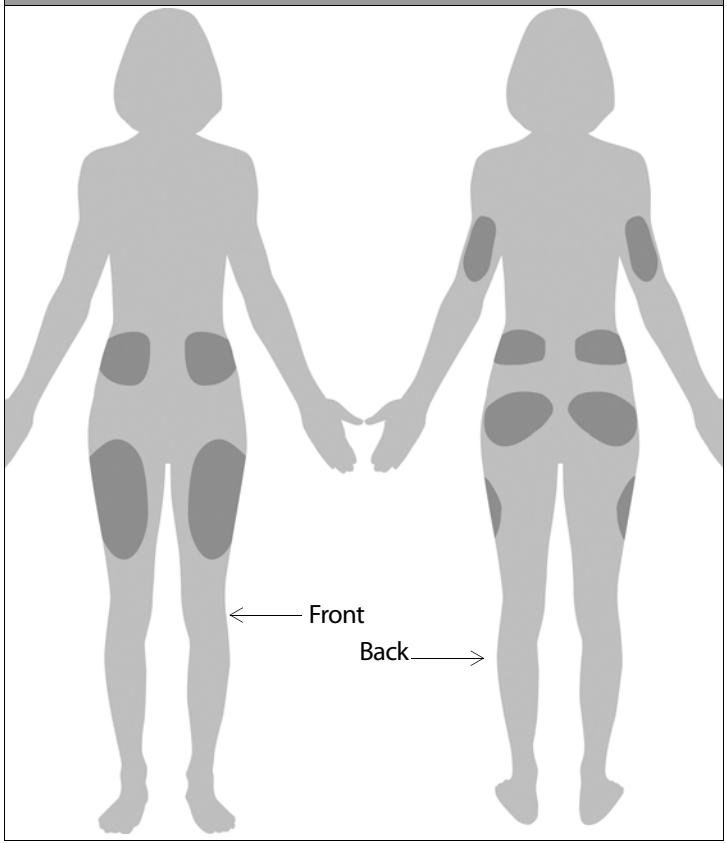
Change the site each time you apply a new Pod. A new infusion site should be at least 2.5 cm (1″) away from the last site. (Using the same location repeatedly may reduce insulin absorption.)

CAUTION

Do NOT apply the Pod within 5.0 cm (2″) of your navel or over a mole or scar, where insulin absorption may be reduced.

TIP To help avoid condensation from occurring in the viewing window, make sure both your Pod and your insulin are at room temperature.

Figure 5-13: Infusion Sites



Prepare the infusion site

You can reduce the risk of infection at the infusion site by following aseptic technique and disinfecting the infusion site. Before applying a new Pod, ***always***:

1. Wash hands with soap and water.
2. Use soap to wash the infusion site.

NOTE Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.

3. Dry the site with a clean towel.
4. Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and gently rub outward in a circular motion.
5. Let the site air-dry thoroughly. Do not blow on the site to dry it.

Apply the new Pod

Prepare the Pod for applying to your infusion site:

1. To remove the needle cap on the underside of the Pod, pull it upward (Figure 5-14). Do not remove needle cap until instructed by the PDM.

NOTE When you remove the needle cap, a drop of insulin may be visible at the end of the needle.

Figure 5-14

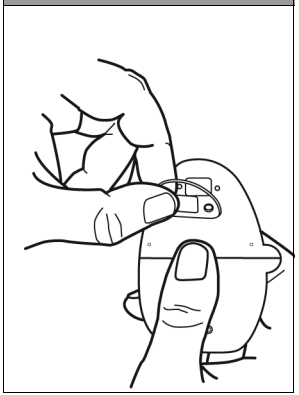
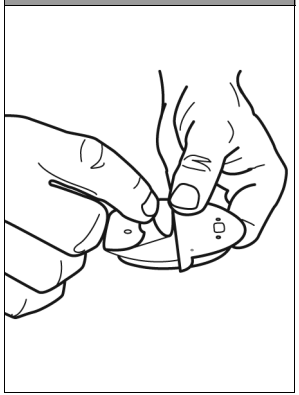


Figure 5-15

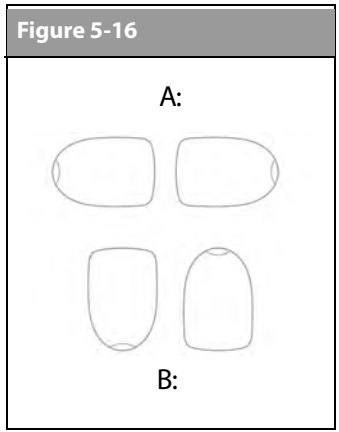


2. Using the pull tabs, remove and discard the white paper backing from the adhesive tape (Figure 5-15).
3. Apply the Pod to the prepared infusion site. Press firmly to secure it to your skin.

TIP For the Pod to work best, apply it:

1. Crosswise or at a slight angle on your abdomen, hip, upper back, or buttocks (see A in Figure 5-16)
2. Up and down or at a slight angle on your upper arm or thigh (see B in Figure 5-16)
3. At least one inch away from the last site

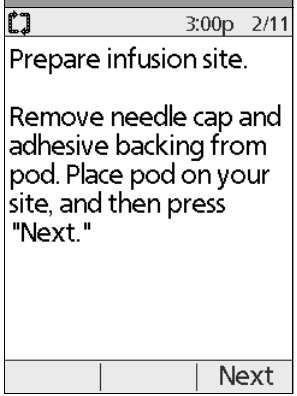
Figure 5-16



NOTE The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products. Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

4. After you securely apply the Pod, press **Next** (Figure 5-17).

Figure 5-17


3:00p 2/11
Prepare infusion site.
Remove needle cap and adhesive backing from pod. Place pod on your site, and then press "Next."
Next

CAUTION

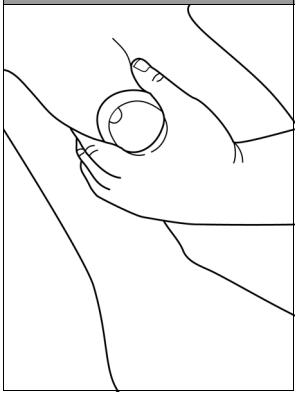
The adhesive is designed for one-time use. Once removed, a Pod cannot be reapplied.

Insert cannula and begin insulin delivery

1. To insert the soft cannula, press **Start** (Figure 5-18).

Figure 5-18

Figure 5-19



WARNING

If you are applying a Pod in a place that does not have a lot of fatty tissue or is very lean, pinch the skin around the Pod (Figure 5-19) after you press **Start**, and hold it until the cannula inserts. Occlusions may result in lean areas if you do not use this technique.

The Pod automatically inserts the soft *cannula* below your skin. It takes a few seconds to complete the insertion process. Once the cannula is inserted, the Pod delivers a *prime bolus* to fill the cannula with insulin (Figure 5-20).

Figure 5-20

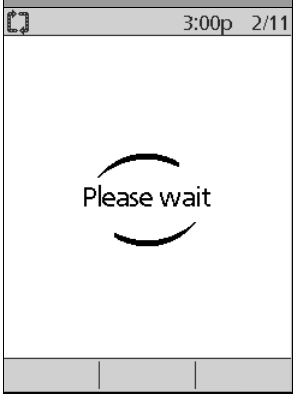
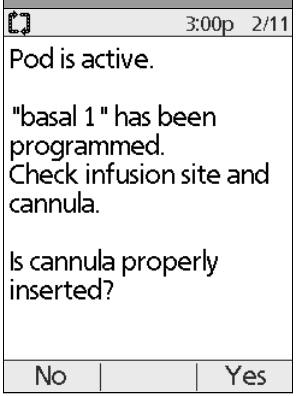


Figure 5-21



NOTE You will hear a click when the cannula inserts.

WARNING Check the infusion site after insertion to ensure that the cannula was properly inserted. It is also a good idea to check your blood glucose about two hours after after each Pod change and to check the infusion site periodically. If the cannula is not properly inserted, hyperglycemia may result.

WARNING If you observe blood in the cannula, check your blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

Once the soft cannula is inserted, the PDM indicates that the Pod is active (Figure 5-21).

Figure 5-21 also displays a reminder to check the infusion site and cannula. Make sure the Pod is securely attached to your skin. You can see the cannula through the small viewing window on the Pod.

NOTE To help avoid condensation from occurring in the viewing window, make sure both your Pod and your insulin are at room temperature.

2. Press **Yes** if you can see that the cannula is properly inserted. The PDM returns to the **Status** screen.

   Or press **No** if you see a problem with the cannula. The PDM instructs you to deactivate the new Pod (Figure 5-22). Press **Discard** to restart the process with a new Pod.

Figure 5-22

   Or press **Back** to return to the previous screen.

WARNING

NEVER inject insulin (or anything else) into the fill port while the Pod is on your body. Doing so may result in unintended or interrupted insulin delivery.

Check Pod Status

To check Pod status, if the PDM is turned off, press and hold the **Power** button to display the **Status** screen. If the PDM is on, press **Back** until you reach the **Status** screen. (If you press and hold the **Power** button, you will turn off the PDM instead.) Or, from the **Home** screen, press **Status**.

The PDM automatically checks the status of the Pod. The PDM then displays the current reservoir volume, PDM battery level, last blood glucose, last bolus dose, active basal program, and any alarm conditions. See Chapter 6, Using the Personal Diabetes Manager, for details of what you see on the **Status** screen.

NOTE

Once a Pod is activated and communicates with the PDM, it can only receive commands from that PDM, not from any other.

If the Pod goes into hazard alarm condition and the PDM is unable to communicate with it to turn off the alarm, you can turn it off manually. See the end of Chapter 11, Communication Failures, for instructions.

Suspend Insulin Delivery

Sometimes you may need to briefly stop insulin delivery (for example, when editing an active basal program or changing the time or date). The OmniPod System lets you suspend all insulin delivery for up to 2 hours. While in suspension, the Pod beeps once every 15 minutes, reminding you that insulin delivery is suspended.

NOTE At any time during a suspension period, press **Resume** to resume the basal program that was running when you suspended insulin delivery.

NOTE Extended boluses and temporary basal rates will be cancelled when you suspend insulin delivery.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend**; then press **Select**.

NOTE If a temporary basal or *extended bolus* is in process, the menu item is **Suspend/cancel** instead, and options for canceling these programs also appear in the menu. If these options appear, choose **Suspend insulin delivery**.

2. Enter how long you want to stop all insulin delivery, from 30 minutes to 2 hours in 30-minute increments (Figure 5-23), then press **Enter**.

Figure 5-23

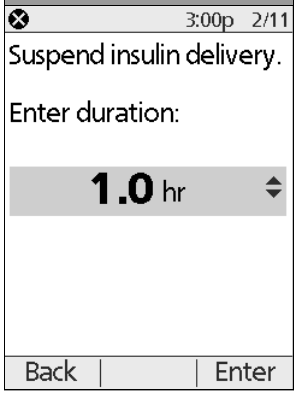
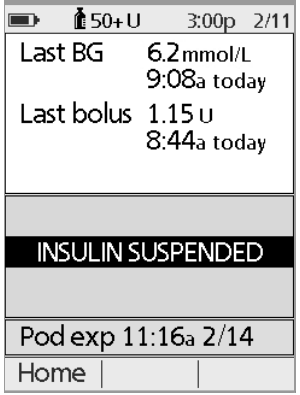


Figure 5-24



3. Press **Confirm** to confirm that you want to halt all insulin delivery (basal and bolus). The PDM beeps and an on-screen message lets you know that insulin delivery is indeed suspended (Figure 5-24).

   The Pod beeps every 15 minutes until the end of the suspension period. The **Status** screen shows INSULIN SUSPENDED until you resume insulin delivery (see "Resume Insulin Delivery" below).

At the end of the suspend time, a Pod *Advisory alarm* occurs (Figure 5-25).

Figure 5-25

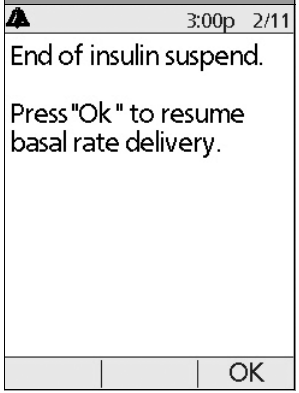
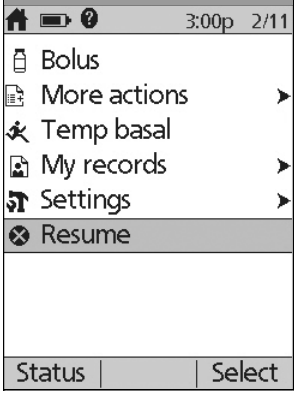


Figure 5-26



4. To resume your programmed basal rate, press **OK**.

NOTE The Advisory alarm repeats every 15 minutes until you press **OK**.

WARNING Insulin delivery will *not* resume until you press **OK**. If you do not press **OK** to resume insulin delivery, you could develop hyperglycemia (high blood glucose).

Resume Insulin Delivery

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Resume** (Figure 5-26); then press **Select**.
2. Press **Confirm** to restart the *basal program* for that time segment.

Avoid Infusion Site Infections

- Always wash your hands and use aseptic technique to prepare the infusion site before applying a Pod.
- Do not apply a Pod to any area of skin with an active infection. If you are unsure whether to use a specific site, ask your healthcare provider.
- At least once a day, use the Pod's viewing window to check the site for signs of infection and to confirm that the soft cannula is securely in place.
- Be aware of the signs of infection, including pain, swelling, redness, discharge, or heat at the site. If you suspect an infection, immediately remove the Pod and apply a new one in a different location. Then call your healthcare provider.
- Change the Pod as instructed by your healthcare provider.

Get the Most From Your Pod

Avoid extreme temperatures

The Pod's operating temperature is between 5° C and 40° C (between 40° F and 104° F). Under normal circumstances, your body temperature will keep the Pod well within this range.

Do NOT expose a Pod to direct sunlight for long periods of time. It is recommended that you remove your Pod prior to using hot tubs, whirlpools, or saunas. These conditions could expose the Pod to extreme temperatures and may also affect the insulin inside the Pod.

Remember to check your blood glucose levels frequently before and after removing the Pod. Check with your healthcare provider for guidelines on removing the Pod for extended periods.

Insulin degrades at high temperatures and will freeze near 0° C (32° F). Check the insulin manufacturer's instructions for use.

Water and your Pod

The Pod is waterproof to a depth of 7.6 m (25') for up to 60 minutes (IPX8). After exposure to water, rinse off the Pod with clean water and gently dry it with a towel.

Do not expose your Pod to water at depths greater than 7.6 m (25') or for more than 60 minutes. Check often to make sure the Pod and soft cannula are securely attached and in place. If the cannula is not properly inserted, hyperglycemia may result.

The PDM is not waterproof. Do not place it in or near water.

Safe storage

Store unopened Pods in a cool, dry place. Extreme heat or cold can damage Pods and cause them to malfunction. If Pods are exposed to extreme temperatures, allow them to return to room temperature before use.

Pods are sterile unless their packaging is opened or damaged. Do NOT apply or use a Pod if its sterile packaging is opened or damaged, as this may increase the risk of infection or serious injury.

CHAPTER 6

Using the Personal Diabetes Manager

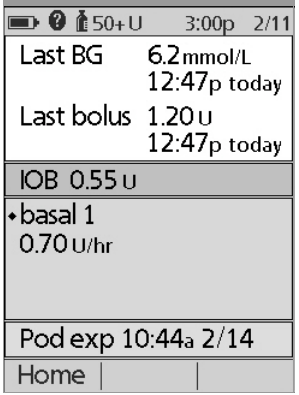
The Status Screen

When a Pod is active and the PDM is turned on, the PDM establishes communication with the Pod to obtain a status check. During the status check, the PDM collects information from the Pod about bolus deliveries, active basal programs, and Pod expiration. The information obtained is then displayed in the status screen, which shows the System's current operating status.

The **Status** screen (Figure 6-1) displays:

- Time, date, and result of last blood glucose checked or entered manually
- Time, date, and total amount of last bolus delivered
- Amount of insulin on board, (IOB) if suggested bolus calculator is in use
- Name and rate of active basal program or temp basal program
- "Ext bolus," the amount of insulin, and the delivery time remaining if an extended bolus is being delivered

Figure 6-1



- "INSULIN SUSPENDED" if insulin delivery has been suspended
- Time and date when the Pod will expire

NOTE If a Pod has not yet been activated (as during Pod changes), the screen displays "No active Pod. Would you like to activate a Pod now?" (See Chapter 5, Using the Pod, for details on activating a Pod.)

Insulin gauge and display

One of the important icons on the **Status** screen is the insulin gauge at the top of the screen. It indicates how much insulin is left in the Pod's reservoir. As the reservoir empties, the icon changes to indicate the amount of insulin remaining.

Next to the insulin gauge, the PDM displays the number of units remaining in the Pod. As long as more than 50 units remain, the gauge displays "50+ U." Once the reservoir volume drops to 50 units, the gauge counts down unit by unit. When the volume falls below 5 units, the display changes to "LOW."

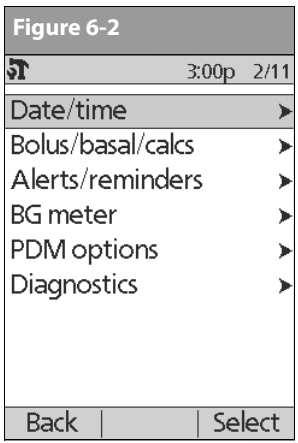
TIP Regularly checking the insulin gauge enables you to plan Pod changes easily. For example, if you know you will need approximately 20 units during your work day and the insulin gauge shows only 17 units remaining, you can either take a new Pod with you or change it before you leave for the day.

PDM settings

You can adjust the PDM settings to meet your individual needs.

1. From the **Status** screens, press **Home**.
2. Use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
3. Choose **System setup**, then press **Select**.
4. Choose an option from the **System setup** list, then press **Select** (Figure 6-2). Check with your *healthcare provider* before making any changes.

Figure 6-2



The System Setup Menu

The **System setup** menu lets you personalize the settings that control the OmniPod System. These include:

- Date and time
- *Bolus doses*, *basal rates*, and bolus calculator settings
- Alert and reminder notifications
- Blood glucose meter settings and tags
- PDM options
- Diagnostics

You and your healthcare provider entered initial System settings using the Setup Wizard (see Chapter 2, Getting Started). After setup, you can use the **System setup** menu to customize or change those settings, as described in this chapter.

Reset the Date or Time

Occasionally, you need to change date and time settings (for example, to adjust for daylight savings time or after resetting the PDM). As a safety feature, you can change date and time settings only when the Pod is deactivated or when insulin delivery is suspended (see Chapter 5, Using the Pod).

1. Suspend insulin delivery.

If you are changing the Pod, you can reset the date or time without suspending by changing the date or time before activating the new Pod.

2. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
3. Choose **System setup**, then press **Select**.
4. Choose **Date/time**, then press **Select**.
5. Choose either **Time** or **Date**, then press **Edit**.

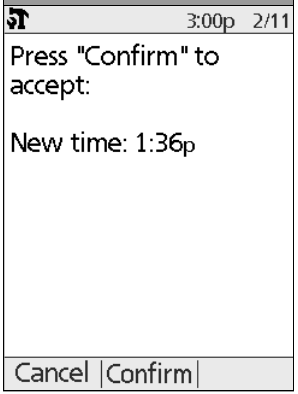
Reset the time

1. To enter the current time, press the **Up/Down Controller** buttons. Press and hold the button to increase or decrease the time faster.

2. Press **12/24 hr** to choose either a 12-hour or 24-hour clock, then press **Enter** (Figure 6-3).

Figure 6-3

Figure 6-4



3. Press **Confirm** to accept the new time (Figure 6-4).

Reset the date

1. Press the **Up/Down Controller** buttons to choose the current year, then press **Next**.
2. Choose the current month, then press **Next**.
3. Choose the current day, then press **Next**.
4. Choose the date format to be displayed by the PDM, then press **Select**.
5. Press **Confirm** to accept the new date and format.

If you suspended insulin delivery to change the time or date, remember to resume insulin delivery. If you changed the time or date during the Pod change process, remember to activate a new Pod.

Change Bolus and Basal Settings

You and your healthcare provider entered initial bolus and basal System settings using the Setup Wizard. Using the **System setup** menu, you can edit all the OmniPod System bolus and basal settings as your needs change. Check with your healthcare provider before making any changes.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Bolus/basal/calcs**, then press **Select**.

4. Choose one of the options (Figure 6-5a and Figure 6-5b), then press **Select**. Each option is described below.

Figure 6-5a

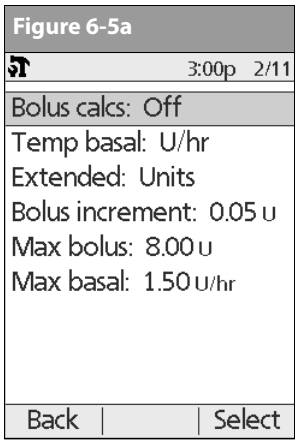
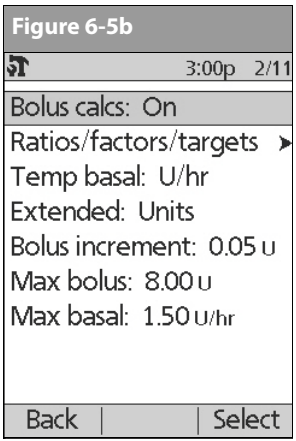


Figure 6-5b



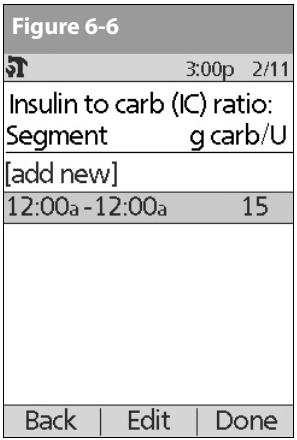
Bolus calcs

When the *suggested bolus calculator* is turned **Off** and you want to turn it **On**, press **On** and follow these steps:

1. **Target BG and correct-above value**—You can edit existing time segments and add segments, up to a total of four.
   a. To edit an existing *target BG* time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, target BG value, and correct-above value (*correction threshold*). Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   c. When you have completed all the time segments you want, press **Done**, then **Save**.
2. **Min BG for calcs** (minimum blood glucose value allowed for calculating boluses)—Use the U**p/Down Controller** buttons to enter a new minimum BG, then press **Next**.

3. **Insulin to carb (IC) ratio**—You can edit existing time segments and add segments, up to a total of four.
   a. To edit an existing *IC ratio* time segment, choose the segment, then press **Edit** (Figure 6-6). Use the **Up/Down Controller** buttons to choose a new start time, end time, and IC ratio. Press **Next** after each entry.

Figure 6-6



   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and IC ratio. Press **Next** after each entry.
   c. When you have completed all time segments, press **Done**, then **Save**.
4. **Correction factor**—You can edit existing time segments and add segments, up to a total of four.
   a. To edit an existing *correction factor* time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, and correction factor. Press **Next** after each entry
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and correction factor. Press **Next** after each entry.
   c. When you have completed all time segments, press **Done**, then **Save**.
5. **Reverse correction**—Choose **On** or **Off**, then press **Next**.
6. **Insulin action (duration)**—Use the **Up/Down Controller** buttons to choose a *duration of insulin action*, then press **Done**.
7. Press **OK**.

Ratios/factors/targets

When the suggested bolus calculator is turned **On**, you can view and change all the settings using the **Ratios/factors/targets** menu option. Choose **Review all settings**, then press **Select** (Figure 6-7a). Or choose one setting from the menu, then press **Select** (Figure 6-7b). The steps are the same whether you choose all settings or individual ones.

NOTE When the suggested bolus calculator is turned **Off**, the **Ratios/factors/targets** option does not appear in the **Bolus/basal/calcs** menu.

Figure 6-7a

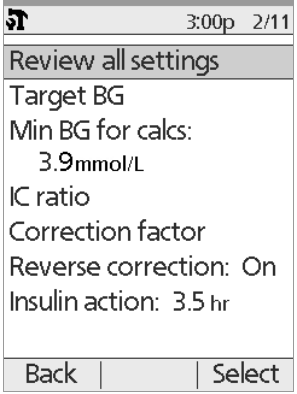
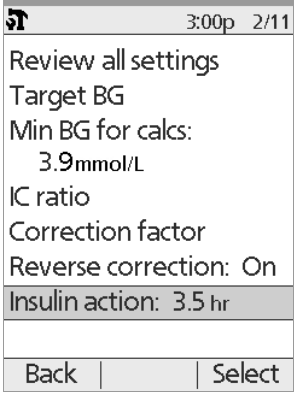


Figure 6-7b



1. **Target BG and correct-above value**—You can edit existing segments and add segments, up to a total of four.
   a. To edit an existing target BG time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   c. When you have completed all the time segments you want, press **Done**, then **Save**.
2. **Min BG for calcs** (minimum blood glucose value allowed for calculating boluses)—Use the **Up/Down Controller** buttons to enter a new minimum BG, then press **Enter**.
3. **Insulin to carb (IC) ratio**—You can edit existing time segments and add segments, up to a total of four.
   a. To edit an existing IC ratio time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, and IC ratio. Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and IC ratio. Press **Next** after each entry.

c. When you have completed all time segments, press **Done**, then **Save**.

4. **Correction factor**—You can edit existing time segments and add segments, up to a total of four.
   a. To edit an existing correction factor time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, and correction factor. Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and correction factor. Press **Next** after each entry.
   c. When you have completed all time segments, press **Done**, then **Save**.
5. **Reverse correction**—Choose **On** or **Off**, then press **Select**.
6. **Insulin action (duration)**—Use the **Up/Down Controller** buttons to choose a duration of insulin action, then press **Enter**.

Temp basal

Choose **%**, **U/hr** , or **Off** to set the mode for temporary basal rates and presets, then press **Select**.

Extended

Choose **%**, **Units**, or **Off** to set the mode for extended boluses, then press **Select**.

Bolus increment

Choose **0.05**, **0.10**, **0.50**, or **1.00** units for bolus increments, then press **Select**.

Max bolus

Use the **Up/Down Controller** buttons to enter the maximum bolus dose you can take, then press **Enter**.

Max basal rate

Use the **Up/Down Controller** buttons to enter the maximum basal rate you can choose, then press **Enter**.

Some settings have preset defaults, but all settings are changeable. See the Appendix for a list of System specifications, including preset default settings.

For additional details on bolus and basal settings, see Chapter 3, Understanding and Adjusting Basal Rates, and Chapter 4, Understanding and Delivering Bolus Doses.

Alert and Reminder Notifications

In addition to automatic safety alarms (see Chapter 10, Alerts and Alarms), the OmniPod System offers a number of notifications that you can set to help you manage your diabetes. These features are optional. You can turn alert or reminder notifications on or off at any time.

Notifications you can use are:

BG (blood glucose) reminder: Reminds you to check your blood glucose. Choose from **On** or **Off**. The default setting is **Off**. When the reminder is on, the PDM asks you each time you enter a bolus dose whether you want to set a BG reminder, and you can then choose a time interval, in 1/2-hour increments.

Expiration: Notifies you when the Pod is nearing the 72-hour expiration time. Choose a period from 1 to 24 hours before expiration, in 1-hour increments. The default setting is 4 hours. You will hear 2 sets of beeps every minute for 3 minutes. The notification will repeat every 15 minutes until you press **OK** to acknowledge it.

Low reservoir: Notifies you when insulin in the Pod reaches a certain level, so you can plan ahead to change the Pod. Choose a level from 10 to 50 units, in 5-unit increments. The default setting is 10 units.

Auto-off: Alerts you if the PDM does not receive a Pod status within a predefined period of time. Obtain Pod status by pressing and holding the PDM's **Power** button. This alert can be especially reassuring if you are prone to hypoglycemia unawareness. Choose a time period from 1 to 24 hours, in 1-hour increments, or choose **Off**. The default setting is **Off**.

The Auto-off alert will escalate to a hazard alarm if ignored and will result in the deactivation of your active Pod. Be sure to respond to the alert when it occurs.

Turning the PDM on by inserting a blood glucose test strip does *not* send a Pod status to the PDM.

Bolus reminders: Notifies you if you have not delivered a meal bolus, manually or using the suggested bolus calculator, between the times you specify. Choose **On** or **Off** and choose up to 6 time segments.

Reminder alerts: Pod beeps when a program is in process (see Chapter 3, Understanding and Adjusting Basal Rates, and Chapter 4, Understanding and Delivering Bolus Doses, for details). These include:

- Temporary basal in process
- Extended bolus in process

Choose **On** or **Off**. The default setting is **On**.

Confidence alerts: The Pod or PDM beeps in response to your instructions, so you become familiar with the operation of the OmniPod System and feel confident that you are getting the insulin you need. These notifications include:

- Bolus delivery started
- Bolus delivery completed
- Extended bolus started
- Extended bolus completed
- Temporary basal rate started
- Temporary basal completed

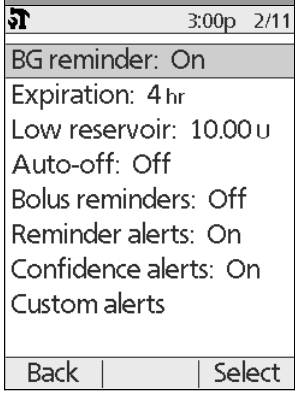
Choose **On** or **Off**. The default setting is **On**.

Custom alerts: Displays text reminders that you enter, at times that you select. You can choose to receive a notification **Daily**, **One time only**, or **Off**. You can change or delete these notifications at any time.

Set alert and reminder notifications

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Alerts/reminders**, then press **Select**.
4. Choose the notification you want to set (Figure 6-8), then press **Select**.

Figure 6-8



5. For all except **Bolus reminders** and **Custom alerts**, choose the desired option or set the desired value, then press **Select** or **Enter**.

6. For **Bolus reminders**
   - Use the **Up/Down Controller** buttons to choose **On** or **Off**, then press **Select**.
   - If you chose **On**, you are taken to a new screen where you can add, edit or delete reminders:

     To add a Bolus reminder
     a. Use the **Up/Down Controller** buttons to choose **[add new]**, then press **New**.
     b. Choose a start time, then press **Next**.
     c. Choose an end time, then press **Save**.

     To edit a Bolus reminder
     a. Choose the bolus reminder you wish to edit, then press **Edit**.
     b. Choose **Edit**, then press **Select**.
     c. Enter a new start time, then press **Next**.
     d. Enter a new end time, then press **Save**.

     To delete a Bolus reminder
     a. Choose the bolus reminder you wish to delete, then press **Edit**.
     b. Choose **Delete** then press **Select**.
     c. Press **Delete** to remove the bolus reminder.

7. For **Custom alerts**
   - Use the **Up/Down Controller** buttons to choose **[add new]**, then press **New**.
   - To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns names in numerical order, such as alert 1, alert 2, alert 3.

     If you want to give a different name to the notification:
     a. Use the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down-arrow symbol on the screen indicates the character you are changing.
     b. Press the middle soft key to move the underscore to the next character.
     c. Enter each character one at a time. For example, for a reminder to pick up a prescription, you might enter R, x (Figure 6-9 on next page). (A blank character or space is the first and last option in the scrolling menu.)

Figure 6-9

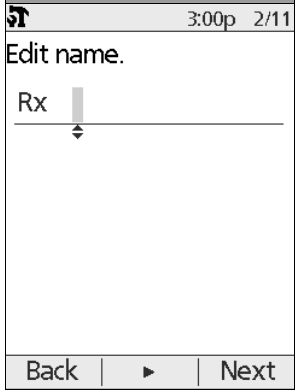
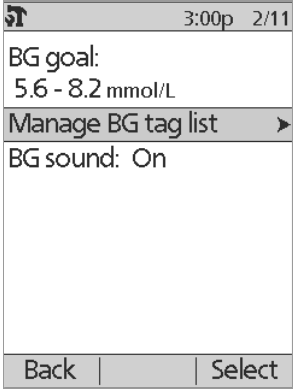


Figure 6-10



d. Press **Next**.

- Enter the time of day for the notification, in 30-minute increments, then press **Next**.
- Choose **Daily**, **One time only**, or **Off**, then press **Select**.

NOTE Custom alerts will repeat every 15 minutes until acknowledged.

TIP You can change or delete alert and reminder notifications at any time.

Change Blood Glucose Meter Settings

You can adjust blood glucose (BG) meter settings:

- BG goal lower and upper limits (for BG history)
- Manage BG tags list
- BG sound—**On** or **Off**

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **BG meter**, then press **Select**.
4. Choose the setting you want to change (Figure 6-10), then press **Select**.

Change BG goal limits

To change the **BG goal** limits, press **Edit**, change either or both values, then press **Save**.

Manage the blood glucose tags list

You can create up to 15 custom blood glucose tags and hide any of the standard tags you do not plan to use. Standard BG tags are shown first on the screen (Figure 6-11a), followed by custom tags, then **[add new]** (Figure 6-11b). For more information about tagging BG readings, see Chapter 7, Checking Your Blood Glucose.

Figure 6-11a

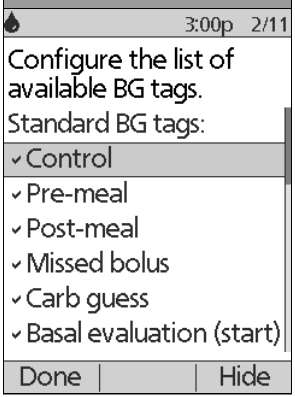
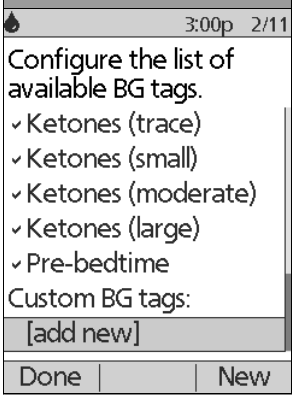


Figure 6-11b



1. To hide or show a standard BG tag, choose the tag, and press **Show** (if it is marked as hidden) or **Hide**.

   Tags you choose to show will be checkmarked; hidden ones will not be.

2. To add a custom tag, choose **[add new]** at the end of the list of custom tags, then press **New**.

   In the **Edit name** screen, either:

   a. Press **Save** to save the new tag with the default name, **custom tag1**, **custom tag2,** and so on; or

   b. Use the **Up/Down Controller** key to choose letters and numbers for a name, followed by the middle soft key to move forward one space. Then press **Save**.

3. To delete a custom tag, choose the tag, press **Delete**, then press **Delete** again. Or press **Cancel** to leave the tag unchanged.

Change BG sound

To change **BG sound**, choose **On** or **Off**, then press **Select**.

Customize the Personal Diabetes Manager

Additional options let you customize how the PDM operates:

PDM lock: "Locks" the buttons on the PDM. The default setting is **Off**. This safety feature can help avoid accidentally changing basal rates or giving boluses.

Screen time-out: The screen turns off after a time interval that you set, which occurs if you have not pressed any buttons on the PDM. This setting preserves battery power by turning off the screen when you are not using it. Set it at the lowest setting to maximize battery life.

NOTE Press and hold the **Power** button to turn the screen back on. In some cases, if it has been less than 5 minutes since the screen timed out, pressing the **Power** button returns you to the same screen you were using. If it has been longer than 5 minutes, the PDM brings you to the **Status** screen.

Backlight time-out: The backlight is on by default while you are using the PDM. The time-out setting dims the backlight and causes the screen to dim when you have not used it within the time interval that you set. Set at the lowest setting to maximize battery life.

TIP For extra brightness on the PDM screen, press and hold the **User Info/Support** button (**?**) for 2 seconds. This enables a "bright mode." The screen will remain in this mode until the PDM times out or you turn it off. To preserve battery life, use this feature only when necessary.

Set PDM options

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **PDM options** (Figure 6-12 on the following page), then press **Select**.

Figure 6-12

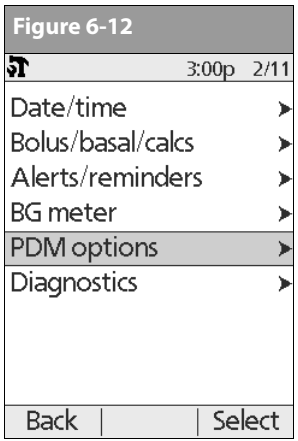
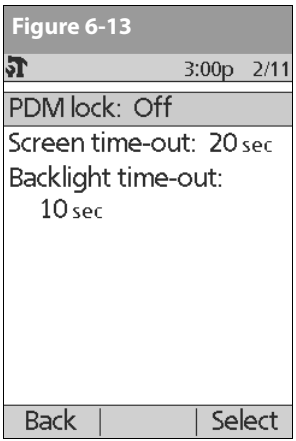


Figure 6-13



4. Choose one of the options (Figure 6-13), then press **Select**.

Set PDM lock

Choose **On** or **Off**, then press **Select**.

CAUTION

If you choose **On**, other PDM options and most other soft keys are locked and will not respond to button presses. To use them, you must first set **PDM lock** to **Off**.

Set the Screen time-out

Choose a time interval, then press **Select**.

When the screen times out and goes black, turn it on again by pressing the **Home/Power** button.

Set the Backlight time-out

Choose a time interval, then press **Select**.

When the screen dims, turn it on again by pressing any button. The PDM will ignore the usual command and relight the screen.

NOTE

The lowest setting will drain the battery the least.

Set Diagnostic Functions

The **Diagnostics** screen allows you to instantly confirm how the System is working or to completely update settings entered during setup (see Chapter 2, Getting Started). Options include:

Check alarms: Confirms that all alarms work properly when needed. When you select this function, the PDM beeps and vibrates, then the Pod beeps.

WARNING

If the PDM fails to beep, immediately call Customer Care. If a Pod is active and fails to beep, change the Pod immediately (see Chapter 5, Using the Pod). Continuing to use the System in these situations may put your health and safety at risk.

Reset PDM (soft reset): Restores all settings in the PDM to the factory defaults.

CAUTION

Resetting the PDM deletes all basal programs, temp basal presets, carb presets, bolus presets, and all suggested bolus settings. Before you use this feature and delete these settings, be sure you have a written record of the information you need. History records will not be deleted.

NOTE

As a safety feature, you cannot reset the PDM when a Pod is active. You must first deactivate the Pod.

Diagnostic options

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Diagnostics**, then press **Select**.

To check alarms

1. Choose **Check alarms**, then press **Select**.
2. Press **OK**. The PDM beeps three times and vibrates three times. If a Pod is active, it then beeps three times.

CAUTION

Check the alarm function at every Pod change.

To reset the PDM

1. Choose **Reset PDM**, then press **Select**.
2. If the Pod is deactivated, the PDM asks for confirmation and reminds you that you will lose all user settings (Figure 6-14). Press **Confirm** to reset the PDM.

   If the Pod is still active, you will be unable to reset the PDM (Figure 6-15). Press **OK** to return to the **Diagnostics** menu.

Figure 6-14

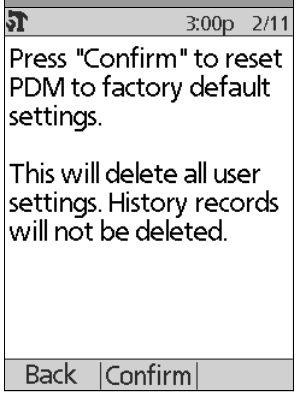
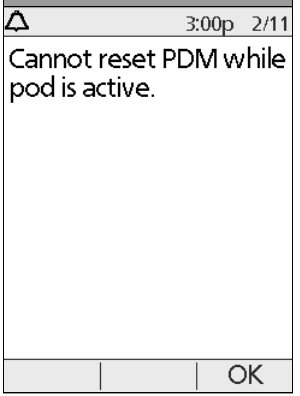

3:00p 2/11
Press "Confirm" to reset PDM to factory default settings.
This will delete all user settings. History records will not be deleted.
Back
Confirm

Figure 6-15



TIP Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset your PDM, having these settings handy will make setup very easy.

Set a Notification to Vibrate

For certain notifications, you can choose vibration instead of beeps or vibration followed by beeps, instead of only beeps. If you set the vibration alert, the PDM will vibrate for:

- Blood Glucose reminders
- Missed Bolus reminders
- Custom Alerts
- "No active Pod" reminders

NOTE The PDM cannot be set to vibrate for hazard or advisory alarms.

To change the type of alert

1. Use the **Up/Down Controller** button to choose **Settings**; then press **Select**.
2. Choose **Vibration alert**, then press **Select**.
3. Choose **Vibrate**, **Vibrate then beep**, or **Off** (beep only), then press **Select**. (**Vibrate then beep** means the PDM will repeat the reminder twice using vibration. After that, it uses beeps.)

   Or press **Back** to return to the **Settings** menu.

Get the Most from Your PDM

Keep it handy

Wireless communication technology means you don't have to keep the PDM right next to the Pod for the Pod to work. Once you set your basal program, the Pod continues to deliver your basal program 24 hours a day, regardless of the location of the PDM. However, you still need the PDM to deliver a bolus, change the basal rate, and so on. You can store the PDM conveniently inside an article of clothing (like a shirt pocket) or put it discreetly into a drawer, briefcase, or purse.

Communicating with the Pod

When you use the PDM to communicate with the Pod, hold the PDM within 61 cm (24") of the Pod. If you wear the Pod on your abdomen, holding the PDM in your hands when pressing the buttons should be close enough.

Water and your PDM

The PDM is not waterproof. Do NOT place it in or near water.

Do NOT use IV Prep wipes, alcohol swabs, soap, detergent, or solvents to clean the screen or any other part of the PDM.

Avoid extreme temperatures

Extreme operating temperatures can affect PDM batteries and interfere with System operation. Avoid using the PDM in temperatures below 5°C (40°F) or above 40°C (104°F).

Do not store or leave the PDM where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

Never attempt to test your blood glucose while your PDM is connected via USB cable to a computer. Doing so could result in electrical shock.

Electrical interference

The PDM is designed to withstand normal radio interference and electromagnetic fields. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve (see Chapter 11, Communication Failures).

Only connect a USB cable to your PDM when downloading data to a computer. Other PDM functions are disabled while a USB cable is connected, and the PDM cannot communicate with the Pod.

The PDM is compatible only with Windows®-based operating systems. Do not connect a USB cable from your PDM or attempt to download your data to a computer using a non-Windows®-based operating system, as the PDM may alarm and require a reset.

When you connect a USB cable to the PDM, only use a cable that is less than or equal to 2.7 meters (9 feet) in length.

CHAPTER 7

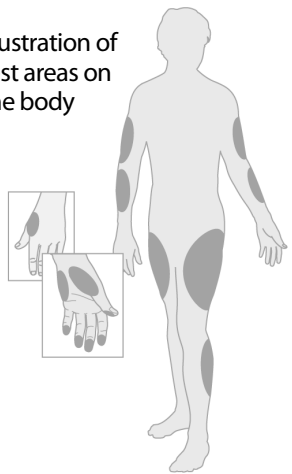
Checking Your Blood Glucose

The Built-in FreeStyle® Blood Glucose Meter

With the FreeStyle® *blood glucose meter*, you can check your blood *glucose* on your finger, hand, forearm, upper arm, thigh, or calf (Figure 7-1).

Figure 7-1

Illustration of test areas on the body



Checking with the FreeStyle® blood glucose meter requires a very small sample size, 0.3 microliter of blood.

Most *healthcare providers* recommend checking on your hand, arm, thigh, or leg when blood glucose values are stable: before meals and before bedtime. However, when *blood glucose* is changing, it is best to test on your fingers. Blood from the fingertips may show these changes sooner than blood from other sites.

WARNING

We recommend that you test on your fingers if you are checking for *hypoglycemia* (low blood glucose) or if you suffer from *hypoglycemia unawareness*. Blood from the fingertips may show changes in blood glucose sooner than blood from other sites.

You may also want to test for low blood glucose:

- When you feel symptoms such as weakness, sweating, nervousness, headache, or confusion
- When you have delayed a meal after taking *insulin*
- When your healthcare provider advises you to do so

CAUTION

This device is intended for self-testing by the user.

WARNING

The system and the FreeStyle® accessories contain small parts that may be dangerous if swallowed.

WARNING

Only use FreeStyle® test strips and FreeStyle® control solution with the system. Using other brands of test strips and control solutions with the system can produce inaccurate results.

WARNING

Never attempt to test your blood glucose while your PDM is connected via USB cable to a computer. Doing so could result in electrical shock.

CAUTION

Please read all the instructions provided in this *User Guide* and practice the testing procedures before using the system and FreeStyle® accessories. Follow the guidance of a healthcare professional for proper blood *glucose* monitoring.

The FreeStyle® Blood Glucose Test Strips

Important test strip information

- Store the blood glucose test strip package between 4° and 30° C (40° and 86° F).
- Use test strips only when the system is within its operating temperature range, between 4° and 40° C (40° and 104° F).
- Keep test strips away from direct sunlight and heat.
- Store test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a blood glucose test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you can gently touch the test strip anywhere when removing it from the vial or inserting it into the test strip port.
- Do not bend, cut, or alter blood glucose tests strips in any way.

WARNING

Do not use strips beyond the expiration date printed on the package, as this may cause inaccurate results.

NOTE

For detailed storage and usage information, refer to the package insert in the box containing the test strip vial.

WARNING

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

The FreeStyle® Control Solution

The FreeStyle® control solution (Figure 7-2) is a liquid that contains a fixed amount of glucose and has two important uses:

- To ensure that your meter and test strips are working together properly
- To practice testing without having to use your own blood

Figure 7-2

When to perform a control solution test

You should perform a control solution test:

- When you suspect that your meter or test strips are not working properly
- When you think your test results are not accurate, or if your test results are not consistent with how you feel
- When you drop or damage your PDM or expose it to liquids
- When your healthcare provider advises you to do so

For information on how to obtain control solution, call Customer Care.

Check that the meter and test strips are working

A control solution test follows the same procedure as a blood glucose reading, except that you use a sample of control solution instead of a drop of blood. (See "Performing a blood glucose reading" later in this chapter.)

When you perform a control solution test, if the reading is within the control solution acceptable range, the meter is working properly.

Control solution expiration date

FreeStyle® control solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward 3 months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle. For example, if you open the control solution on January 15, count forward 3 months to April 15. This is the discard date to record on the bottle, and the date to discard it and begin using a new bottle.

Ensure accurate control solution results

- Replace the cap on the control solution bottle immediately after using it.

Use only FreeStyle® control solution with the system. Other brands of control solution may produce inaccurate results with this system.

Do not use control solution past the expiration date or you may get inaccurate results.

- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when performed between 15° and 40° C (59° and 104° F).

Results from FreeStyle® control solution tests do not reflect your *blood glucose level*.

- The control solution test results should fall within the range printed on the test strip vial label.

The control solution range is a target range for control solution only. It is not a target range for your blood glucose.

If control solution results are out of this range, REPEAT THE TEST.

Out-of-range control solution results

Out-of-range test results may be caused by:

- Expired or bad control solution
- Expired or bad test strip
- Error in performing test
- Code on test strip vial does not match code set in the PDM
- Malfunction of the system
- Control solution test done outside 15° to 40° C (59° to 104° F)

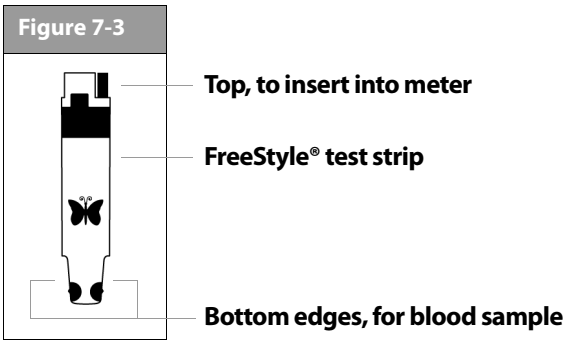
If your control solution test results continue to fall outside the range printed on the test strip vial:

1. The system may not be working properly.
2. Do not use the system to test your blood glucose.
3. Call Customer Care.

Performing a Control Solution Test

1. Grasp the bottom of the test strip with the printed side facing up (Figure 7-3).

Figure 7-3



2. Insert the top of the test strip into the test strip port (Figure 7-4) until it stops. This turns on the PDM and displays the code number on the screen.

NOTE Be ready to adjust the code on the PDM to match the code number on the test strip vial (Figure 7-5).

NOTE If you need to adjust the code number after the PDM has moved to the next screen, just press the **Up/Down Controller** buttons. The code screen reappears and you can adjust the number.

The code number remains on the PDM screen for your reference until you have completed the control test.

Figure 7-4

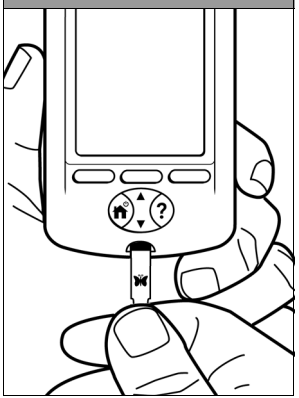
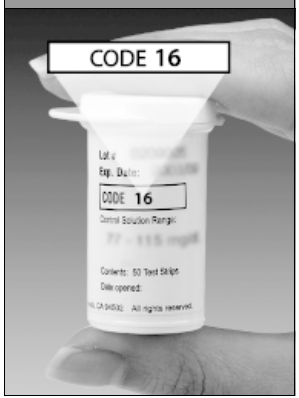


Figure 7-5



WARNING

The code number on the screen should match the code number on the side of your test strip vial (Figure 7-5 on previous page). They must always match, or your results will be inaccurate. (See "Set the blood glucose test strip code" later in this chapter.)

NOTE

From some PDM screens, you cannot access the Freestyle® blood glucose meter. For example, you cannot use the meter while you are activating a Pod or when an alert, alarm, or communication error screen is displayed. In these cases, if you insert a test strip, the PDM beeps to alert you.

3. To help you see the test strip port in reduced lighting, when you insert a test strip into the PDM, you can turn on the port light. Press the middle *soft key* labeled **Light**. To turn the light off, press **Light** again.
4. Wait for the PDM to display "Apply a blood sample to the strip" on the screen (Figure 7-6).

Figure 7-6

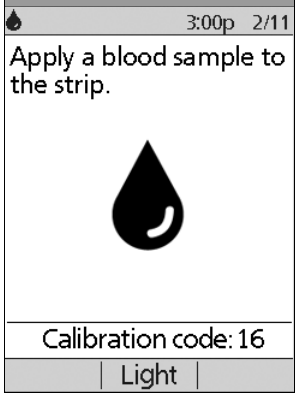
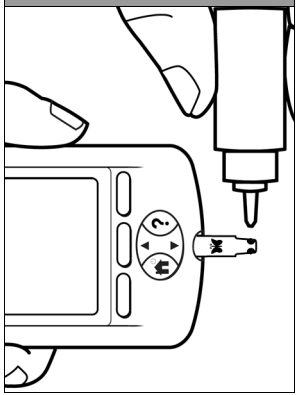


Figure 7-7



5. Gently touch only ONE EDGE of the test strip to the control solution. Specifically, apply the control solution to the test strip edge next to one of the dark-colored half-circles (Figure 7-7). If **BG sound** is set to **On**, the PDM beeps when the test strip is full.

   If you do not apply the sample within 10 seconds, the strip-port light turns off. To turn it on again, press **Light**.

The "Checking" screen appears while the sample is processing (Figure 7-8). The strip-port light turns off when the sample is accepted.

Figure 7-8

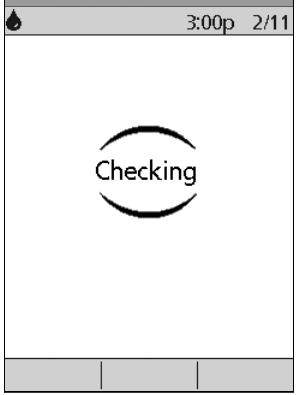
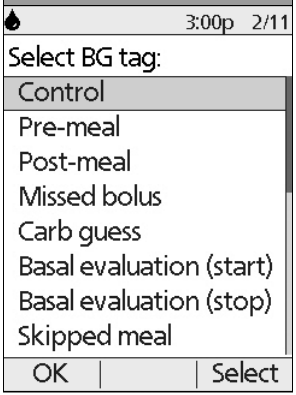


Figure 7-9



NOTE Do not apply control solution to both edges of the test strip.

If **BG sound** is set to **On**, the PDM beeps twice. The result appears on the screen.

6. To mark the result as a control solution result rather than a blood glucose test:
   a. Press **Tag**.
   b. Use the **Up/Down Controller** buttons to select **Control** (Figure 7-9), then press **Select**. You can select a second tag for the test result in the same way.

      NOTE You can select a maximum of 2 tags.

   c. Press **OK**.
7. If you do not want to mark the test as a control solution test, press **Next** instead of **Tag**.

   NOTE If the *suggested bolus calculator* feature is turned **Off**, the **Bolus** soft key appears instead of **Next**.

   NOTE If you mark a test as a control solution test by mistake, you can unmark it: Press **Tag**, select **Control**, then press **Clear**.

8. Compare the control solution test result to the range printed on the test strip vial label. If the result does not fall within the range, repeat the test. If the result still does not fall within the range, call Customer Care.

9. Remove the test strip. If the strip-port light was turned on, it now turns off.

   If you remove the test strip before this step, you will still see the available soft keys.

NOTE Be sure to discard used test strips. (You can only use test strips once.)

Performing a blood glucose reading

Figure 7-10 shows the parts of the FreeStyle® lancing device.

WARNING To ensure accurate results, wash your hands and the test site (for example, your forearm) with soap and water. Do not leave any cream or lotion on the test site. Thoroughly dry your hands and the test site.

Figure 7-10

Cocking handle
Depth settings dial
Depth indicator window
Release button
Clear cap, for testing sites other than the finger
Gray cap, for testing on the fingers

Prepare the lancing device

1. Snap off the cap on the lancing device at an angle (Figure 7-11).

Figure 7-11

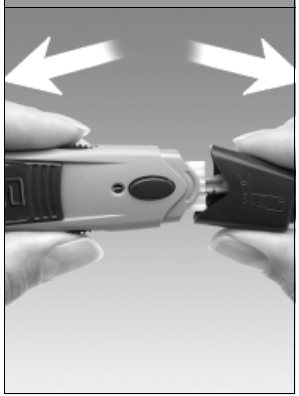
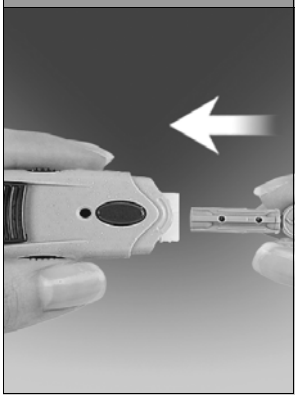


Figure 7-12



2. Insert a new FreeStyle® lancet firmly into the white lancet holder cup (Figure 7-12). Pushing the device into the cup may cock the device, which is fine.
3. Hold the lancet firmly in place with one hand. With your other hand, twist off the rounded top (Figure 7-13).
4. Replace the cap until it snaps or clicks into place (Figure 7-14). Be careful not to touch the exposed needle on the lancet.

Figure 7-13

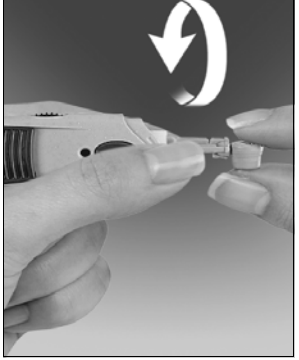
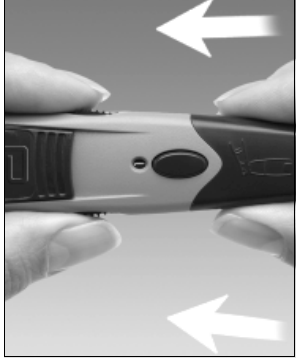


Figure 7-14



NOTE

Use the clear cap to lance at the following test sites: forearm, upper arm, hand, thigh, and calf. Use the gray cap for finger tests only.

5. The lancing device offers four different depth settings. Level 1 is the shallowest depth; level 4 is the deepest. Move the dial to the desired setting as shown in the depth indicator window (Figure 7-15). To lance your finger, we recommend that you start at Level 1. To lance your arm, we recommend that you start at level 2.

Figure 7-15

Figure 7-16

6. Pull out the dark gray cocking handle until it clicks (Figure 7-16). (You may have already cocked the handle in step 2. This is okay.)

You are now ready to perform a blood glucose test.

Insert the blood glucose test strip

1. Insert a new blood glucose test strip into the test strip port until it stops. The test strip port is at the bottom of the PDM.

NOTE

From some PDM screens, you cannot access the Freestyle® blood glucose meter. For example, you cannot use the meter while you are activating a Pod or when an alert, alarm, or communication error screen is displayed. In these cases, if you insert a test strip, the PDM beeps to alert you.

2. To help you see the test strip port in reduced lighting, press the middle soft key labeled **Light**. To turn the light off, press **Light** again.
3. Insert only the top end of the strip into the test strip port, with the dark colored rectangle going into the meter (Figure 7-17

and Figure 7-18).

Figure 7-17

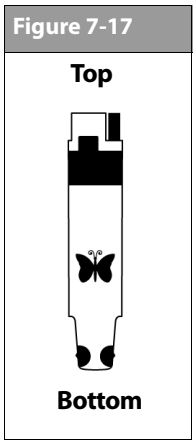
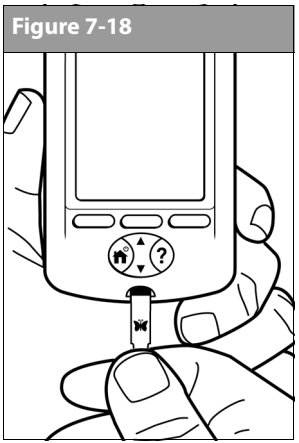


Figure 7-18



NOTE If you do not start the test within 2 minutes, the PDM powers off. To restart the PDM, take out the unused strip and reinsert it, or simply press and hold the **Power** button to turn on the PDM.

Set the blood glucose test strip code

After you insert the strip, the PDM displays a code number (Figure 7-19). This number must match the code on the side of the vial.

Figure 7-19

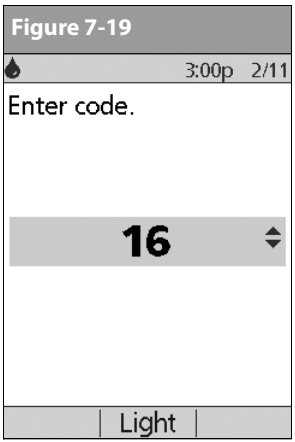
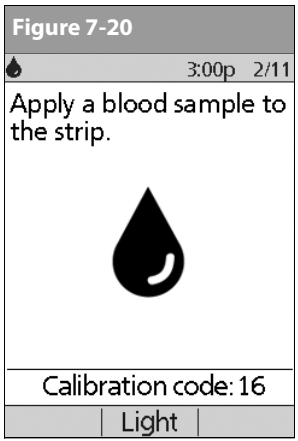


Figure 7-20



To change the code number, press the **Up/Down Controller** buttons until the number matches the number on your vial. The numbers are between 1 and 50.

If you do not adjust the code number within 2 seconds, the next screen appears automatically (Figure 7-20).

NOTE

If you need to adjust the code number after the PDM has moved to the next screen, just press the **Up/Down Controller** buttons. The code screen reappears and you can adjust the number.

The code number remains on the PDM screen for your reference until you have completed the BG test.

WARNING

The code number on the screen should match the code number on the side of your test strip vial (Figure 7-5). They must always match, or your results will be inaccurate.

Lance your finger

1. To stimulate blood flow, keep your hand warm or lower your hand to waist level and gently massage your finger.
2. Set the depth setting on the lancing device (Figure 7-21).
3. Lightly touch the lancing device (with the gray cap) against the side of your fingertip (Figure 7-22).
4. Press the release button.
5. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms.

Figure 7-21

Figure 7-22

Lance your forearm, upper arm, hand, thigh, or calf

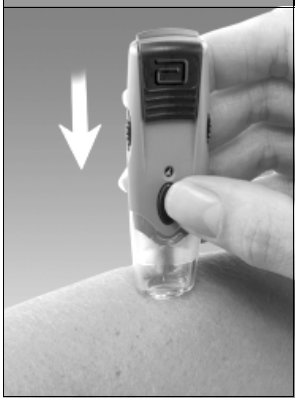
1. To bring fresh blood to the surface of the test site, rub the site vigorously for a few seconds (Figure 7-23) until you feel it getting warm.

Figure 7-23

Figure 7-24

2. Set the depth setting on the lancing device (Figure 7-24).
3. Hold the lancing device (with the clear cap) against the top of your test site.
4. Press the release button. Do not lift up; continue to hold the button and gradually increase pressure against the site for several seconds (Figure 7-25).

Figure 7-25



5. While holding the lancing device on your test site, look through the clear cap. The blood sample should be about the size of a pinhead.
6. Lift the lancing device straight up; be careful not to smear the blood sample on your test site.

CAUTION

Avoid lancing areas with obvious veins or moles, to avoid excess bleeding. Also avoid lancing areas where tendons or bones stick out (for example, hand bones).

Fill the blood glucose test strip with blood

1. Make sure that the strip is in the PDM and the PDM is powered on. If the PDM has powered off, take out the strip and reinsert it (Figure 7-26), or simply press and hold the **Power** button to turn on the PDM.

Figure 7-26

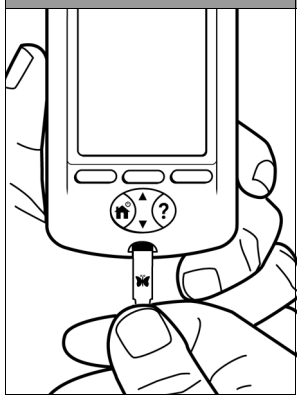
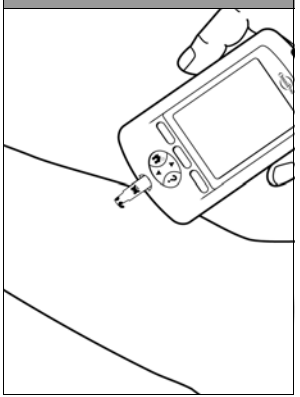


Figure 7-27



2. Bring the strip to the blood sample at a slight angle (Figure 7-27).

   If you do not apply the sample within 10 seconds, the strip-port light turns off. To turn it on again, press **Light**.

   Use only one edge of the blood glucose test strip per test. Do not apply blood to both edges (Figure 7-28). Only use strips once. Discard used strips.

Figure 7-28

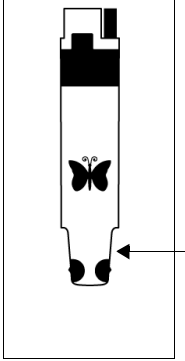
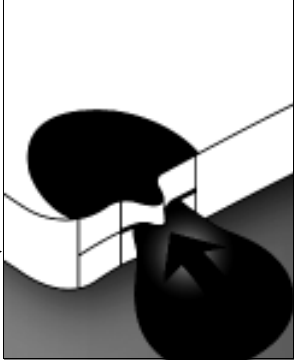


Figure 7-29



The strip pulls the blood into the strip through the edge (Figure 7-29).

CAUTION

Do not:

- Press the strip against the test site
- Scrape the blood onto the strip
- Apply blood to the flat side of the strip
- Apply blood to the strip when it is out of the meter
- Put blood or foreign objects into the test strip port

Wait for the reading

1. Do not pull the test strip away from the sample until you hear 1 beep or see the word "Checking" on the screen (Figure 7-30). This means you applied enough blood and the meter is reading your glucose.
2. If after 5 seconds the PDM does not display "Checking," the sample may be too small. If needed, add more blood to the same edge of the strip for up to 60 seconds from the time of the first application.

   The strip-port light turns off when the blood sample is accepted.

Figure 7-30

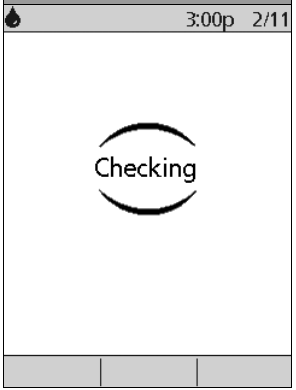
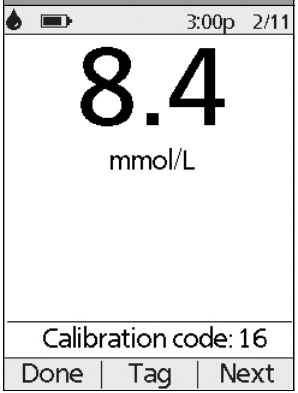


Figure 7-31



3. The reading is complete when you hear 2 beeps (if **BG sound** is turned **On**) and the PDM shows your reading on the screen (Figure 7-31).

   The time the test takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

4. To mark the result as a pre- or post-meal test, to indicate a level of exercise, or to indicate other situations connected to this blood glucose reading, press **Tag**. Then:
   a. Use the **Up/Down Controller** buttons to select a tag, then press **Select** (Figure 7-32).You can select a second tag for the reading in the same way.

      To learn how to manage your list of tags and to add custom tags, see "Manage the blood glucose tags list" in Chapter 6, Using the Personal Diabetes Manager.

Figure 7-32

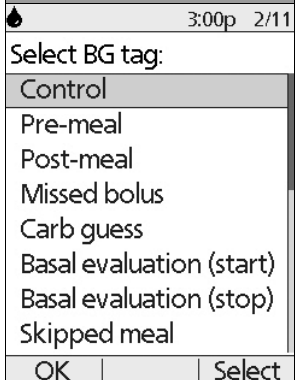


Figure 7-33

   b. Press **OK** to return to the reading screen (Figure 7-31 on the previous page), then press **Next**.
5. If you do not want to mark the test, press **Next** instead of **Tag**.

   NOTE If the suggested bolus calculator feature is turned **Off**, the **Bolus** soft key appears instead of **Next**.

6. Remove the test strip. If the strip-port light was turned on, it now turns off.

Remove the lancet

When you have finished testing, remove the lancet from the lancing device (Figure 7-33). Discard the used lancet properly in a puncture-resistant container.

Blood Glucose Results and the Suggested Bolus Calculator

If the suggested bolus calculator feature is turned **On** when you check your blood glucose, the PDM will display the result. From here, press **Next** to enter carbs (if eating) and have the System calculate a suggested bolus. (See "Suggested Bolus Calculator" in Chapter 4, Understanding and Delivering Bolus Doses.)

NOTE If you use the suggested bolus calculator within 10 minutes after taking a blood glucose reading, or if you store a BG reading (for example, one you enter manually) within the same 10 minutes, the BG value will be populated automatically for use in the suggested bolus calculator process (Figure 7-34).

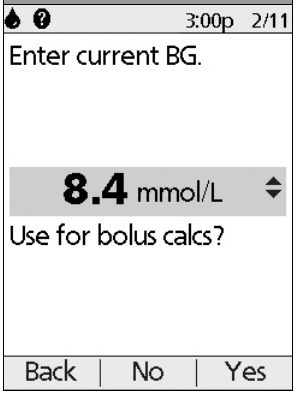
If the suggested bolus calculator feature is turned **Off**, the **Next** soft key does not appear. Instead:

Press **Bolus** to open a screen where you can enter a bolus manually.

Or press **Done** to return to the **Status** screen to see the most recent BG result.

The BG result, either from the PDM or from manual entry, is stored in the System's history, whether suggested bolus calculator is turned **On** or **Off**. (See "Blood Glucose Records" in Chapter 8, Understanding Your Records.)

Figure 7-34



NOTE The **Bolus Entry** screen does not open if:

- A regular bolus is currently in process
- The meter temperature is out of range
- You have tagged this BG reading as a Control
- The BG reading is less than your "Min BG for calcs"
- Insulin is suspended

Entering Blood Glucose Readings Manually

You can enter blood glucose readings manually into the PDM. This is particularly helpful if you use a separate blood glucose meter.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**; then press **Select**.
2. Choose **Add BG reading**, then press **Select**.
3. Use the **Up/Down Controller** buttons to enter the BG reading from your separate meter.

   TIP To enter a "LOW" reading, press the **Up/Down Controller** buttons down until you reach the minimum value (1.1); then press down one more time. To enter a "HIGH" reading, press up until you reach the maximum value (27.8); then press up one more time.

4. Press **Tag** to assign a tag to the reading. Press **OK** when finished. (For an explanation of entering tags, see page 90.)
5. Press **Save** to save the reading.

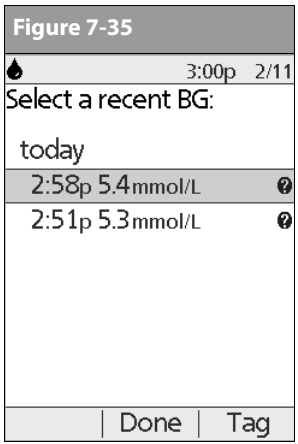
   Or press **Cancel** to return to the **More actions** menu without saving the reading.

Editing Tags

Within 2 hours of a blood glucose reading, you can remove or change a tag or add one. However, you cannot alter a Control tag.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**; then press **Select**.
2. Choose **Assign/Edit BG tags**, then press **Select**.
3. Use the **Up/Down Controller** buttons to choose a reading, then press **Tag** (Figure 7-35). A **User Info/Support** icon (**?**) is shown to the right of any reading to which you have already assigned one or two tags.

Figure 7-35



Or press **Done** to return to the **More actions** menu.

4. Use the **Up/Down Controller** buttons to choose the first tag you want, then press **Select** (Figure 7-36). A diamond icon appears next to selected tags, as in "Pre-meal" in the figure. You can select up to two tags for each BG reading.
5. To remove a selected tag, highlight it and press **Clear**. (The soft key changes from **Select** to **Clear** when you highlight the tag.)

Figure 7-36

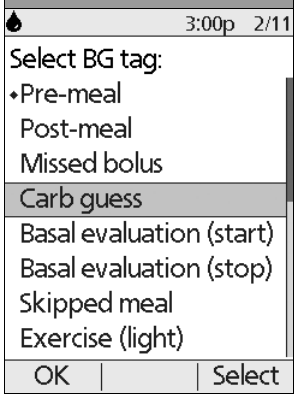
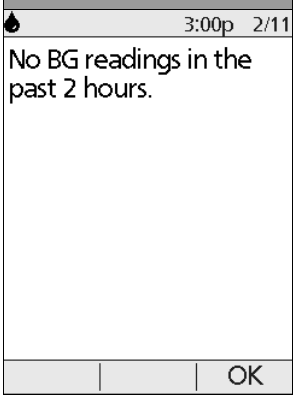


Figure 7-37



6. Press **OK** to return to the list of readings.

If no BG readings have been entered into the PDM within the past 2 hours, you will see the screen in Figure 7-37. Press **OK** to return to the **More actions** menu.

To learn how to manage your list of tags and to add custom tags, see "Manage the blood glucose tags list" in Chapter 6, Using the Personal Diabetes Manager.

Low and High Blood Glucose Readings

WARNINGS!

"LOW" or "HIGH" blood glucose readings can indicate a potentially serious condition requiring immediate medical attention. If left untreated, this situation can quickly lead to *diabetic ketoacidosis (DKA)*, shock, coma, or death.

Low readings

If your reading is below 1.1 mmol/L, the PDM displays: "LOW Treat your low BG!" This indicates severe hypoglycemia (low blood glucose).

Low reading with symptoms

If you get a "LOW Treat your low BG!" reading and feel symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare provider's recommendation to treat hypoglycemia.

Low reading without symptoms

If you get a "LOW Treat your low BG!" reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a "LOW Treat your low BG!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your healthcare provider's recommendation to treat hypoglycemia.

High readings

If your reading is above 27.8 mmol/L, the PDM displays "HIGH Check for ketones!" This indicates severe *hyperglycemia* (high blood glucose).

High reading with symptoms

If you get a "HIGH Check for ketones!" reading and feel symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare provider's recommendation to treat hyperglycemia.

High reading without symptoms

If you get a "HIGH Check for ketones!" reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a "HIGH Check for ketones!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your healthcare provider's recommendation to treat hyperglycemia.

You can add and edit tags for LOW and HIGH BG readings just as you would to any other reading. To add tags, see page 90; to edit tags, see page 92.

Important Health-Related Information

WARNINGS!

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare provider immediately.
- Test results below 3.9 mmol/L mean low blood glucose (hypoglycemia).
- Test results greater than 13.9 mmol/L mean high blood glucose (hyperglycemia).
- If you get results below 3.9 mmol/L or above 13.9 mmol/L, but do not have symptoms of hypoglycemia or hyperglycemia (see Chapter 9, Living with Diabetes), repeat the test. If you have symptoms or continue to get results that fall below 3.9 mmol/L or above 13.9 mmol/L, follow the treatment advice of your healthcare provider.
- If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this *User Guide*, call your healthcare provider immediately.
- Blood circulation is different between the finger and other test sites like the forearm, upper arm, hand, thigh, and calf. You may see differences in blood glucose measurements between the other test sites and your finger after eating, insulin medication, or exercise.
- You may see changes in blood glucose in blood samples from the finger sooner than in blood samples from the forearm and other alternate sites. Vigorous rubbing of the alternate test sites before lancing helps to minimize these differences.
- Do not use during xylose-absorption testing.
- The lancing device is for individual use only and must not be shared.
- For additional information, consult your test strip product information sheet.

CHAPTER 8

Understanding Your Records

Record Keeping

Record keeping is an important part of successful *diabetes* management. The Personal Diabetes Manager (PDM) helps simplify this task. It automatically stores records of insulin-delivery history, *blood glucose* readings, alarms, and *carbohydrates*. The PDM can store over 5,000 records or approximately 90 days' worth of information. Once the memory is full, new information begins to replace the oldest information.

CAUTION

If the PDM batteries run out, data in the memory is at risk. Do NOT remove the old batteries until you have new ones at hand. The PDM protects data in the memory for up to 2 hours after the batteries run out or are removed.

Special symbols in record screens

In the record screens, you may encounter several special symbols:

- Records with a question-mark symbol next to them have additional information available. To see this information, use the **Up/Down Controller** buttons to highlight the record, then press the **User Info/Support** button to view details about that record.
- The record for this item has been "lost."

  NOTE

  If the PDM can no longer communicate with an active Pod, then you must activate a new Pod. The PDM may not be able to communicate with the active Pod because of signal interference or because you have discarded the Pod. If you change the Pod without getting a Status update, any "unconfirmed" records will be "lost." If this occurs, the PDM will not display insulin totals for any day containing "lost" records.

✔ The record for this item is "unconfirmed."

NOTE When you power on the PDM, it will request a status update from the active Pod and then update the insulin history. If the PDM does not receive a status update from the Pod, the PDM will update history with "unconfirmed" records. The next time the PDM receives a status update, it will update these records.

☾ This insulin delivery item spans midnight. The date given is the start date.

Insulin Delivery Records

The PDM stores:

- *Basal rates* (including any rate changes and temporary basals)
- *Bolus doses* (both normal and extended)
- Dates, times, and how long insulin delivery was suspended, and dates and times when it was resumed
- Total daily doses (basal plus boluses) by date

View insulin delivery records

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Insulin delivery**, then press **Select** (Figure 8-1).

Figure 8-1

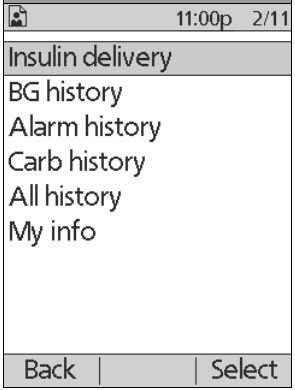
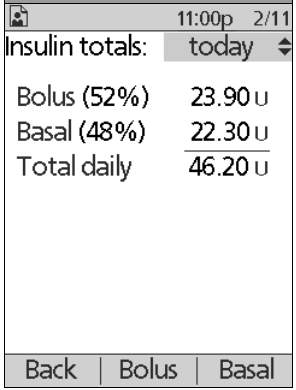


Figure 8-2



The PDM displays a summary of today's information, including total boluses delivered, total basal amount delivered, and total daily dose delivered (Figure 8-2). Press the **Up/Down Controller** buttons to view the summary for previous days.

Wherever you see the **?** symbol, press the **User Info/Support** button to see additional information.

3. To review your basal history by day, press **Basal**.

   The display shows the basal deliveries that have occurred for the current day, most recent first (Figure 8-3 on the next page). The active basal rate or program is indicated by a diamond icon (♦).

Figure 8-3

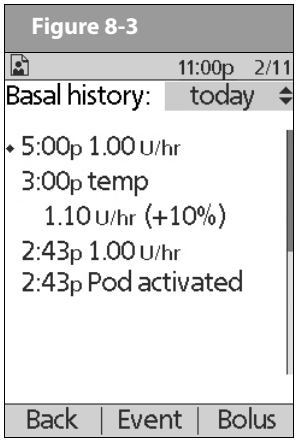
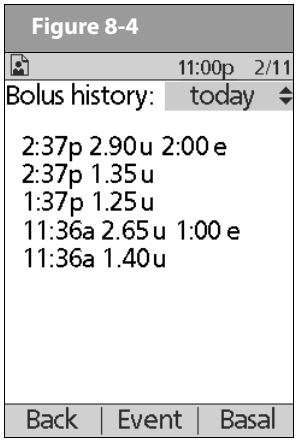


Figure 8-4



For a temporary basal program, the display shows the % adjustment that has been made o the default basal rate. So, in Figure 8-3, "1.10 temp U/hr (+10%)" means that you delivered a temporary basal of 1.10 units per hour, which was 10% more than the default basal. (Notice that two hours later, the basal rate returns to the default.)

Also, the "Pod activated" entry shows what time you applied a new Pod.

Press the **Up/Down Controller** buttons for earlier or later dates.

Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Choose a record, then press the **User Info/Support** button to view details about that record. Record details may include insulin delivery that was interrupted due to a Pod alarm, Pod deactivation, or user cancellation. The screen shows the amount of the bolus or basal that remained undelivered.

4. Press **Day** to return to dates.
5. To review your bolus history by day, press **Bolus**.

   The display indicates whether the bolus was normal or extended (marked "e" in Figure 8-4). Normal and extended boluses are displayed separately even if they were programmed at the same time. Extended boluses are shown with time and duration. If an extended bolus is active, a diamond icon (♦) appears next to it. If a bolus was cancelled, only the amount delivered before cancellation is shown.

   NOTE The amount shown after cancellation may be in 0.05 unit *increments*, even though you may have programmed the bolus increment to be in 0.10 units.

   Press the **Up/Down Controller** buttons for different dates.

   Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to return to dates.

Blood Glucose Records

The PDM stores *blood glucose* records for the past 90 days. You can choose to view individual readings, single-day trends with individual readings, or trends for the previous 7, 14, 30, 60, or 90 days.

View single-day trends

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **BG history**, then press **Select**.

   The PDM displays the current-day trends first (Figure 8-5), including:

   - Number of days and number of blood glucose readings (n)
   - Average blood glucose (Avg BG)
   - Lowest and highest blood glucose (Min/max)
   - The *BG goal* you have set
   - Percentage of readings within the BG goal
   - Percentage of readings above the BG goal
   - Percentage of readings below the BG goal.

Figure 8-5

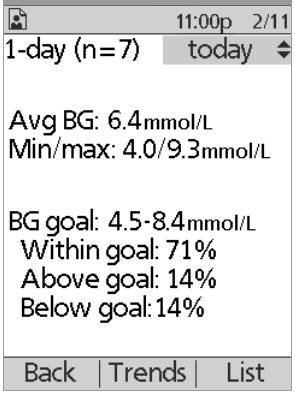
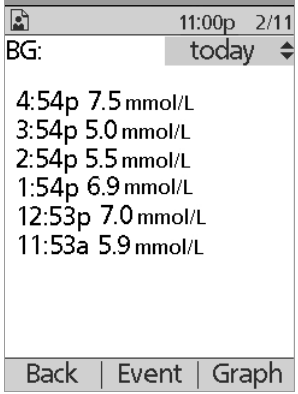


Figure 8-6



NOTE LOW and HIGH readings are included in the number of BG readings (n), but not in calculations or averages.

3. Press **List** to see a list of the current day's readings (Figure 8-6).

In the **List** view, press **Event** to select individual readings. Readings with a question-mark icon next to them have additional information available (Figure 8-7). To see this information, use the **Up/Down Controller** buttons to choose the reading. Then press the **User Info/Support** button to view details about that reading (Figure 8-8).

Figure 8-7

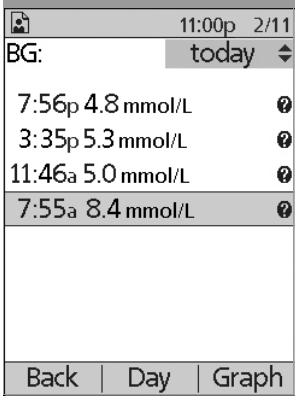


Figure 8-8

4. Press **Close** to return to the **List** view.
5. Press **Graph** to see a graph of the data (Figure 8-9).

View multiple-day trends

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **BG history**, then press **Select**.
3. Press **Trends** to display blood glucose data for the past 7 days.
4. Continue pressing the middle soft key to view trends for the previous 14, 30, 60, and 90 days.

   The PDM displays the same details for multiple days as for single days, plus the average number of BG measurements taken per day (Figure 8-10).

Figure 8-9

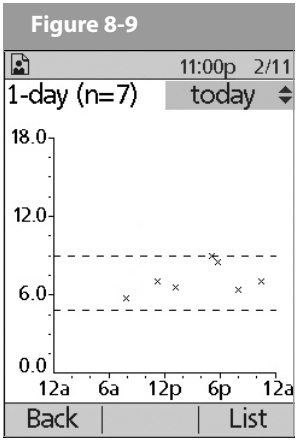
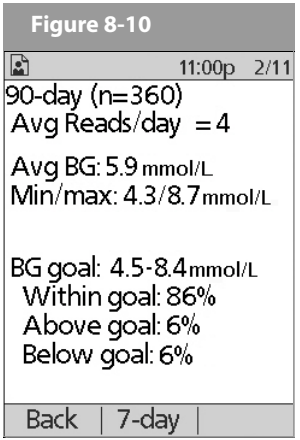


Figure 8-10



5. For the 7-, 14-, and 30-day trends, press **Graph** to see a graph of the trends (Figure 8-11). (Graphs are not available for 60-, or 90-day trends.) Press **Stats** to return to the detail view.

Figure 8-11

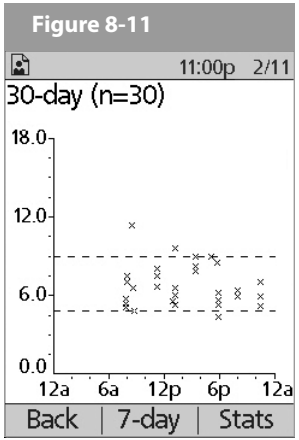
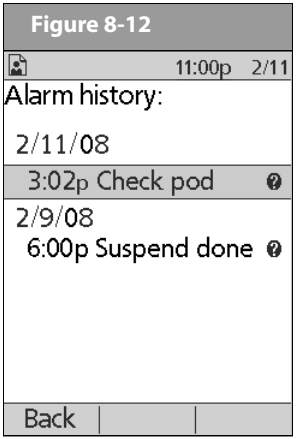


Figure 8-12



6. Press **Back** to return to the single-day trends.

Alarm Records

The PDM lists the entire alarm history for the OmniPod System. The PDM can store over 90 days' worth of alarm records.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Alarm history**, then press **Select**.

   The PDM displays the date, time, and type of each alarm (Figure 8-12).
3. Press the **Up/Down Controller** buttons to see additional screens.
4. Choose an alarm record, then press **User Info/Support** to see more information.

Carbohydrate Records

The PDM displays the record of carbohydrates you have entered.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Carb history**, then press **Select**.

   The PDM displays the date, time, and grams of carbohydrate you have entered (Figure 8-13 on the following page).

Figure 8-13

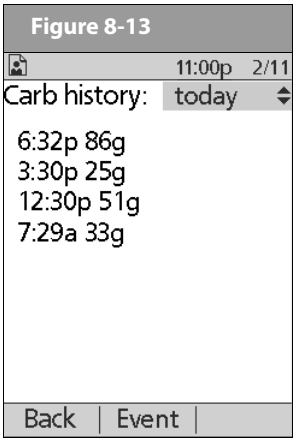
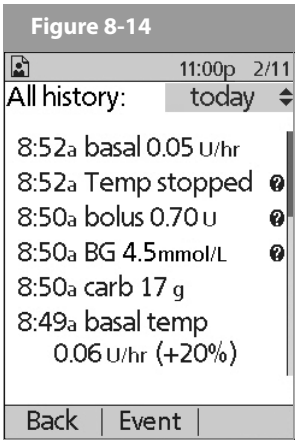


Figure 8-14



3. Press the **Up/Down Controller** buttons to see additional days.

   Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to use the **Up/Down Controller** for dates.

All Records

The PDM displays the combined insulin delivery, blood glucose, alarm, and carbohydrate records.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **All history**, then press **Select**.

   The PDM displays all history for the most recent date (Figure 8-14).
3. Press the **Up/Down Controller** buttons to see additional days.

   Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to use the **Up/Down Controller** for dates.

User Information/Support

You or your healthcare provider may have entered personal contact information during your start-up visit. To view this information, press the **User Info/Support** button (to the right of the **Power** button) while on the **Home** screen. Or follow the steps below to view the information. You can add or change the user information at any time.

You may want to include your name, address, phone, email address, emergency contact and phone, doctor's or healthcare provider's name and phone, prescription numbers, or other information.

The user information screen also displays product information for your OmniPod System (make, model, serial number). You cannot change this information.

TIP The **User Info/Support** icon is also displayed on the suggested bolus screen. For information about the support information displayed on these screens, see Chapter 4, Understanding and Delivering Bolus Doses.

Add or change user information

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **My info**, then press **Select**.
3. Choose **[My info]** (Figure 8-15), then press **Edit**.

Figure 8-15

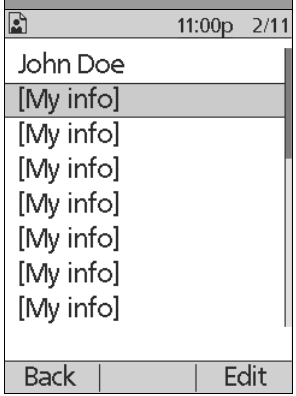
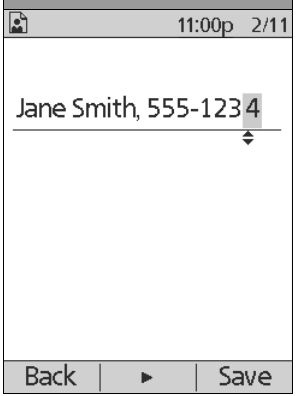


Figure 8-16



4. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down-arrow symbol (⇕) on the screen indicates the character you are changing.
5. Press the middle soft key to move the underscore to the next character.
6. Enter each character one at a time. For example, if you want to enter your address, you might enter 5, 6, 5, [space], M, a, i, n, [space], S, t, [period]. (A blank character or space is the first and last option in the scrolling menu.)

   For your healthcare provider and local phone number, you might enter J, a, n, e, [space], S, m, i, t, h, [comma], [space], 5, 5, 5, [hyphen], 1, 2, 3, 4 (Figure 8-16).
7. Press **Save**.
8. Repeat steps 3–7 for each line of personal information you want to enter or change. Twenty lines are available.

CHAPTER 9

Living with Diabetes

Your Role: Safely Using the OmniPod System

"Before deciding on the OmniPod Insulin Management System, you and your healthcare provider discussed the benefits and potential risks of the OmniPod System, as well as the responsibilities that come with insulin pump therapy."

Most problems are easily avoided by:

- Learning all you can about successful *diabetes* management.
- Being actively involved in your treatment.
- Checking your *blood glucose* levels frequently.
- Washing your hands and disinfecting *infusion sites* to reduce the possibility of infection.
- Being aware of the signs of *hypoglycemia* (low blood glucose), *hyperglycemia* (high blood glucose), and *diabetic ketoacidosis* (DKA). (See "Avoid Lows, Highs, and DKA" later in this chapter.)
- Keeping a diabetes emergency kit with you at all times. (See "Prepare for Emergencies" later in this chapter.)
- Knowing how to contact your healthcare provider in case of an emergency.

If you are unable to use the OmniPod Insulin Management System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the OmniPod System.

Daily Diabetes Management Activities

To ensure proper OmniPod System operation and your continued good health:

- Check your blood glucose frequently
- Inspect the infusion site daily

Check your blood glucose frequently

When you routinely check your *blood glucose level*, you can identify and treat high or low blood glucose before it becomes a problem (see "Avoid Lows, Highs, and DKA" later in this chapter).

Check your blood glucose (BG):

- At least 4 to 6 times a day: when you wake up, before every meal, and before going to bed
- Whenever you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

Inspect the infusion site daily

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for signs of infection, such as pain, swelling, redness, discharge, or heat.

If an infusion site shows signs of infection:

1. Immediately remove the Pod and apply a new one at a different site (see Chapter 5, Using the Pod).
2. Contact your healthcare provider.
3. Treat the infection according to instructions from your healthcare provider. (Refer to Chapter 5, Using the Pod, for how to prepare and care for a site.)

Consider making infusion site checks a part of your regular daily routine (like showering or brushing your teeth). That way, it's easy to remember.

If you observe blood in the cannula, check your blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

Prepare for Emergencies

CAUTION

Keep an emergency kit with you at all times to quickly respond to any diabetes emergency. The kit should include:

- Several new, sealed Pods
- Extra new PDM batteries (at least two AAA alkaline)
- A vial of rapid-acting U-100 insulin (See the warning on page iv of the Introduction for insulins approved for use in the OmniPod System.)
- Syringes for injecting insulin
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- Blood glucose test strips
- Ketone test strips
- Lancing device and lancets
- Glucose tablets or another fast-acting source of carbohydrate
- Alcohol prep swabs
- A copy of the letter from your healthcare provider for airline security (see "Minimize airport security delays" later in this chapter)
- Phone numbers for your healthcare provider and/or doctor in case of an emergency
- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Lows, Highs, and DKA" later in this chapter)

Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

Water and Your Pod

The Pod is waterproof to a depth of 7.6 m (25')for up to 60 minutes (IPX8). After the Pod gets wet, rinse it off with clean water and dry it with a towel.

WARNING

Do NOT expose your Pod to water at depths greater than 7.6 m (25') or for longer than 60 minutes. Check the infusion site often to make sure the Pod and soft cannula are securely applied and in place. If the cannula is not properly inserted, hyperglycemia may result.

CAUTION

The Personal Diabetes Manager (PDM) is not waterproof. Do NOT place it in or near water.

Traveling and Vacationing

Plan for changing time zones

If you're planning a vacation or business trip to a different time zone, you may need to adjust your *basal rate* programs. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct program can be more challenging. Your health-care provider can help with these adjustments.

Take enough supplies

Keeping your emergency kit with you during trips or vacations is especially important (see "Prepare for Emergencies" earlier in this chapter). It may be difficult or impossible to get insulin or supplies in an unfamiliar place. If traveling by air, be sure to pack your supplies in your carry-on luggage. When packing for travel, take more supplies than you think you'll need. Be sure to include:

- Diabetes emergency kit packed in your carry-on luggage
- Enough Pods for your trip, plus a backup supply
- Extra new PDM batteries
- Additional blood glucose meter
- Insulin syringes or pens in case you need injections
- Several vials of insulin or insulin cartridges if you use a pen
- Glucagon kit (Make sure any person you are traveling with knows how to give the injection.)
- Alcohol prep swabs
- Written prescriptions for all medications and supplies

When you travel, be sure to take extra Pod supplies. Please call 1-855-POD-INFO or from outside Canada 647-788-3132 to order additional supplies for your trip.

Minimize airport security delays

Contact the airlines in advance for information on their current security requirements. To make airport security checks go smoothly, be sure you have the following easily accessible:

- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and OmniPod System equipment
- An emergency kit (see "Prepare for Emergencies" earlier in this chapter)
- A list of the supplies you must carry, including the contents of your emergency kit
- Prescriptions for insulin and all supplies, clearly marked with their original pharmacy labels

If the security detector goes off, tell the security screener that you have diabetes and wear an insulin Pod (pump).

NOTE Pods and PDMs can safely pass through airport X-ray machines (see the FCC notice in the Appendix).

Keep supplies accessible

On airplanes and trains, keep these items with you, rather than checking them:

- Personal Diabetes Manager (PDM)
- An emergency kit
- Vials of insulin (cargo area temperatures may affect insulin)
- A copy of your healthcare provider's letter (see "Minimize airport security delays")
- Prescriptions for insulin and supplies
- Snacks, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of a physician at your final destination, in case of emergency

Avoid Lows, Highs, and DKA

You can avoid most risks related to using the OmniPod System by practicing proper techniques and by acting promptly at the first sign of trouble. You can avoid potential problems by knowing the signs of hypoglycemia (low blood glucose), hyperglycemia (high blood glucose), and diabetic ketoacidosis (DKA). The easiest and most reliable way to avoid these conditions is to check your blood glucose often.

General precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.
- If you have technical problems with your OmniPod System and cannot resolve them, do not hesitate to call Customer Care.

Hypoglycemia (low blood glucose)

Hypoglycemia can occur even when a Pod is working properly. Never ignore the signs of low blood glucose (no matter how mild). If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect that your blood glucose level is low, check your BG level to confirm.

Hypoglycemia unawareness is a condition in which you do not realize when your blood glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the OmniPod System's blood glucose reminder and check your blood glucose more frequently. See "Alert and Reminder Notifications" in Chapter 6, Using the Personal Diabetes Manager, for how to set the reminder.

Symptoms of hypoglycemia

Never ignore these symptoms:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety

To avoid hypoglycemia (low blood glucose)

Make sure your blood glucose is at least 5.6 mmol/L before driving or working with dangerous machinery or equipment. Hypoglycemia may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of hypoglycemia.

- Work with your healthcare provider to establish individualized *blood glucose targets* and guidelines.
- Keep a fast-acting *carbohydrate* with you at all times to respond quickly to low blood glucose. Examples of fast-acting carbs are glucose tablets, hard candies, or juice.
- Teach your friends, family members, and colleagues to recognize the signs of hypoglycemia, so they can help if you develop *hypoglycemia unawareness* or a severe adverse reaction.
- Keep a glucagon injection kit with your emergency supplies. Teach friends and family members how to give a glucagon injection in case you have severe hypoglycemia and become unconscious.

Periodically check the expiration date of your glucagon kit to make sure it has not expired.

Always carry medical identification (emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, ***frequent blood glucose checks are the key to avoiding potential problems***. Detecting low blood glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in any and all areas listed above.

To treat hypoglycemia (low blood glucose)

Any time your blood glucose is low, treat it immediately. Check it every 15 minutes while you are treating, to make sure you don't overtreat the condition and cause blood glucose levels to rise too high.

Even if you cannot check your blood glucose, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone. Waiting to treat symptoms could lead to severe hypoglycemia, which can quickly lead to shock, coma, or death.

1. If blood glucose is below 3.9 mmol/L, eat or drink 15 grams of fast-acting carbohydrate, such as glucose tablets, juice, or hard candy (see "How much is 15 grams of carbohydrate?" below).

Do NOT use chocolate or candy bars to treat low blood glucose. Their fat content slows down glucose absorption.

2. Check blood glucose again after 15 minutes.
3. If blood glucose remains low, take another 15 grams of carbohydrate. Contact your healthcare provider as needed for guidance.
4. Repeat steps 2 and 3 until blood glucose is within the *BG goal*.
5. Investigate possible cause for hypoglycemia to avoid similar problems in the future (see "Possible causes of hypoglycemia (low blood glucose)" on the next page).

How much is 15 grams of carbohydrate?

Examples of fast-acting foods:

Three 5-gram glucose tablets, or four 4-gram tablets

118 milliliters (4 ounces) of apple or orange juice

6 Lifesavers or similar hard candy

1/2 can of regular (non-diet) soda

2 tablespoons (30 milliliters) of table sugar, honey, or corn syrup

Teach people you trust (like family members and close friends) how to give a glucagon injection. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.

Possible causes of hypoglycemia (low blood glucose)

Possible cause of low	*Suggested action*
Incorrect basal program	Confirm that correct basal program is active. Confirm that PDM time is set correctly. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Incorrect bolus timing ***Bolus too large***	Take bolus with food. Check blood glucose before giving meal bolus; if necessary, adjust bolus. Check bolus size and timing. Do NOT overcorrect for post-meal glucose levels. Check carb intake. Consult healthcare provider for guidance.
Incorrect target blood glucose levels ***Incorrect correction factor (sensitivity factor)*** ***Incorrect insulin-to-carb ratio***	Consult healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia ***Hypoglycemia unawareness***	Consult healthcare provider about hypoglycemia unawareness and about raising target blood glucose levels.
Unplanned physical activity	If blood glucose is below 5.6 mmol/L, eat a snack before activity. Consult your healthcare provider about using a temporary (temp) basal rate.

Possible cause of low	*Suggested action*
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check blood glucose before, during, and after activity and treat as necessary. NOTE Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Low carbohydrate intake prior to activity	Consume carbohydrate before activity, especially if you have not decreased insulin beforehand.
Alcohol consumption	Check blood glucose before going to bed. Consult healthcare provider for guidance.

Hyperglycemia (high blood glucose)

Insulin Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If an *occlusion* (interruption of insulin delivery from the Pod) occurs, your blood glucose can rise rapidly.

An occlusion may result from a blockage, Pod malfunction, or from using old or inactive insulin. If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

Symptoms of hyperglycemia (high blood glucose)

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

Hyperglycemia symptoms can be confusing. Always check your blood glucose before you treat for hyperglycemia.

To avoid hyperglycemia (high blood glucose)

Check your blood glucose at least 4–6 times a day (when you wake up, before each meal, and before going to bed). In addition, always check it:

- If you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

To treat hyperglycemia (high blood glucose)

Always check your blood glucose levels frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your BG level to drop too far.

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to the BG goal.
2. If your blood glucose is 13.9 mmol/L or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check blood glucose again after 2 hours.
5. If blood glucose levels have not decreased, take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
6. If you feel nauseated at any point, check for ketones and call your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" later in this chapter).
7. If blood glucose remains high after another 2 hours (a total of 4 hours), replace the Pod. Use a new vial of insulin to fill the new Pod. Then:
   - Contact your healthcare provider for guidance.
   - Drink eight ounces of water every 30 minutes until blood glucose is within BG goal.

If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

8. Investigate possible cause for hyperglycemia to avoid similar problems in the future (see "Possible causes of hyperglycemia (high blood glucose)" below).

Possible causes of hyperglycemia (high blood glucose)

Possible cause of high	*Suggested action*
Expired insulin	Deactivate and remove used Pod. Apply new Pod filled with insulin from a new vial.
Insulin exposed to extreme temperatures	
Infusion site in or near a scar or mole	Deactivate and remove used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove used Pod. Apply a new Pod in a different location. NOTE Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.

Possible cause of high	*Suggested action*
Empty Pod	Deactivate and remove used Pod. Apply a new Pod in a different location.
Incorrect basal program	Confirm that correct basal program is active. Confirm that PDM time is set correctly. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Incorrect bolus timing	Check carb intake. Take bolus with food. Check blood glucose before giving meal bolus; if necessary, adjust bolus. Consult healthcare provider for guidance.
Bolus too small	

Possible cause of high	*Suggested action*
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Blood glucose value greater than 13.9 mmol/L (with ketones present) before exercise	Do NOT exercise when ketones are present. (Blood glucose increases with exercise when ketones are present.) Consult healthcare provider for guidance.
Infection or illness	See "Sick days" later in this chapter.
Medication change	Consult your healthcare provider about sick-day guidelines and about medication changes.
Weight loss or gain	Consult your healthcare provider for guidance.
Menstrual cycle	
Pregnancy	

NOTE Check with your healthcare provider for guidance on any of the causes or suggested actions above.

Diabetic ketoacidosis (DKA)

Insulin Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If insulin delivery from the Pod is interrupted (an occlusion), your blood glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but totally preventable—emergency that can occur if you ignore high blood glucose levels.

If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

Symptoms of DKA

Nausea and vomiting

Abdominal pain

Dehydration

Fruity-smelling breath

Dry skin or tongue

Drowsiness

Rapid pulse

Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose and check for ketones to rule out DKA.

To avoid DKA

The easiest and most reliable way to avoid DKA is by **checking your blood glucose at least 4–6 times a day.** Routine checks allow you to identify and treat high blood glucose before DKA develops.

To treat DKA

- Once you have begun treatment for high blood glucose, check for ketones. Check for ketones any time your blood glucose is 13.9 mmol/L or above.
- If ketones are negative or trace, continue treating for high blood glucose.
- If ketones are present, and you are feeling nauseated or ill, immediately call your healthcare provider for guidance.
- If ketones are positive, but you are not feeling nauseated or ill, replace the Pod, using a new vial of insulin.
- Check blood glucose again after 2 hours. If blood glucose level has not declined, immediately call your healthcare provider for guidance.

If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

Handling Special Situations

Sick days

Any physical stress can cause your blood glucose to rise, and illness is a physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your blood glucose more often (at least once every 2 hours) to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Diabetic ketoacidosis (DKA)" earlier in this chapter).

To handle sick days

- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can.
- Adjust bolus doses, if necessary, to match changes in meals and snacks.
- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.
- Check your blood glucose every 2 hours and keep careful records of results.
- Check for ketones when blood glucose is 13.9 mmol/L or higher.
- Follow your healthcare provider's guidelines for taking additional insulin on sick days.
- Drink plenty of noncaffeinated fluids to prevent dehydration.

  NOTE If you are well enough to eat, drink sugar-free beverages. However, if you are too sick to eat solid foods, alternate between sugar-free beverages and those containing sugar.

- Call your healthcare provider immediately if you have:
  - Persistent nausea
  - Vomiting for more than 2 hours
  - High blood glucose or ketones that stay high even though you take extra insulin
  - Low blood glucose with nausea and vomiting

Exercising, playing sports, or working hard

Check your blood glucose levels before, during, and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

For some contact sports, you may want to remove the Pod.

Be sure to check your blood glucose levels before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a used Pod.

If possible, avoid wasting Pods by planning removal times that coincide with a scheduled Pod replacement.

If you will need to remove the Pod for more than 1 hour, ask your healthcare provider to recommend appropriate guidelines.

X-rays, MRIs, and CT scans

The Pod and PDM may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove your Pod and put it and the PDM outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

The Pod and PDM can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

Surgery or hospitalization

For scheduled surgeries or hospitalization, you should tell the doctor/surgeon or hospital staff about your insulin Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.

Always carry medical identification and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

CHAPTER 10

Alerts and Alarms

Safety Checks

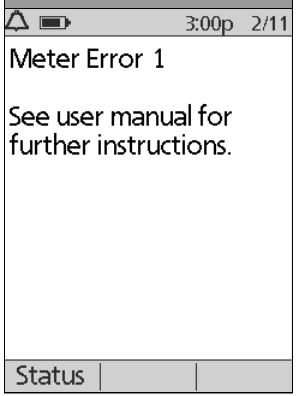
The OmniPod System has a very important safety feature: It can check its own functions and let you know when something needs attention. When you turn on the Personal Diabetes Manager (PDM), the System automatically performs a series of safety checks. To make you aware of a serious or potentially serious condition, the System sounds an alarm and displays an on-screen message. The message has instructions for taking care of the alarm condition. Alarm conditions are easy to handle. They are not a problem if you attend to them promptly.

Blood Glucose Meter Alerts

These alerts let you know about an error in the blood glucose meter, test strip, sample, or results. The PDM beeps and displays an error message number, as in Figure 10-1.

If you are having symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this *User Guide*, call your healthcare professional.

Figure 10-1



The following table explains what the message could mean and what you should do.

Alert error message	*Possible causes*	*Action*
Meter Error 1 See user manual for further instructions.	• Blood sample is too small. • Problem with the test strip. • Problem with the meter. • Very low *blood glucose*: less than 1.1 mmol/L.	1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow the recommendations of your *healthcare provider* for treating *hypoglycemia*. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work, or the error persists, call Customer Care.
Meter Error 2 See user manual for further instructions.	• Problem with the test strip. • Problem with the meter. • Very high blood glucose: above 27.8 mmol/L. • HIGH control solution applied when temperature is too cold. (This applies only to control solution labeled HIGH.)	1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow the recommendations of your healthcare provider for treating *hyperglycemia*. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work or the error persists, call Customer Care.

Alert error message	*Possible causes*	*Action*
Meter Error 3 See user manual for further instructions.	• Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter, or applying blood before the Blood Drop and Test Strip symbols display. • Problem with the test strip. • Problem with the meter.	1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 4 See user manual for further instructions.	• Problem with the test strip. • Problem with the meter.	1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 2. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 6 See user manual for further instructions.	• Blood sample was applied while the code number was being changed.	1. Retest using a new test strip. Do not press any buttons or *soft keys* while applying blood or control solution to the test strip. 2. If the error persists, call Customer Care.

Alarms

The OmniPod System provides alarms to make you aware of serious or potentially serious conditions. When a condition occurs that requires your attention an Advisory Alarm or a Hazard Alarm will sound. Advisory alarms beep intermittently and inform you about a condition that requires your attention. Hazard alarms are continuous tones and occur when either the Pod or PDM is in a serious condition. During an alarm the PDM will display an on screen message with instructions for taking care of the alarm condition. Be sure to respond to all alarms when they occur.

Details on how to handle an Advisory or a Hazard Alarm are below:

Many alarms (such as ***Auto-off***) will escalate and result in deactivation of the active Pod if ignored. Be sure to respond to all alarms when they occur.

Advisory Alarms

Advisory alarms tell you about a condition that requires your attention. Each advisory alarm beeps intermittently. When you hear an advisory alarm, first turn on the PDM to display the **Status** screen. The PDM communicates with the Pod, if necessary, and the screen displays a message describing the alarm and how to resolve it. All advisory alarms are time-sensitive and require a response. Some advisory alarms escalate to hazard alarms if you do not respond within a certain time period (as noted in the following table).

Some advisory alarms are controlled by levels you set in the **Settings** screen. One example is the level at which the ***Low reservoir volume*** alarm sounds.

Hazard Alarms

Hazard alarms occur either when the Pod is in a very serious condition or something is wrong with the PDM. Hazard alarms are continuous tones and each has an on-screen message. Follow the instructions in the message to fix the alarm situation. For details, see the following table.

When a hazard alarm occurs in the Pod, all insulin delivery stops. Failing to address the situation could result in hyperglycemia. If you had a temp basal or extended bolus running when the hazard occurred, the PDM will remind you of this.

Due to the serious nature of hazard alarms, you must act promptly to resolve them.

1. Acknowledge the alarm condition by pressing **OK**, which silences the alarm.
2. Deactivate and remove the active Pod (see Chapter 5, Using the Pod).
3. Activate and apply a new Pod (see Chapter 5, Using the Pod).

10 Alerts and Alarms

If you ever need to return the PDM for repair or replacement, contact your healthcare provider for instructions on going back to treatment by injections.

Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset your PDM, having these settings handy will make setup very easy.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
End of insulin suspend. Press "Ok" to resume basal rate delivery.	Advisory Alarm	Pod	2 sets of beeps every minute for 3 minutes. Repeats every 15 minutes until insulin delivery is resumed.	Press **OK** to resume insulin delivery at programmed *basal rate*. WARNING: Insulin delivery will not resume until you press **OK**. If you do not press **OK** to resume insulin delivery, you could develop hyperglycemia (high blood glucose).
Auto-off alert	Advisory Alarm	Pod and PDM	2 sets of beeps every minute for 15 minutes. Escalates to ***Auto-off*** hazard alarm if not acknowledged within 15 minutes.	Press **OK** to acknowledge.. WARNING: The Auto-off alert will escalate to a hazard alarm if ignored and will result in the deactivation of your active Pod. Be sure to respond to the alert when it occurs.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Auto-off. Remove pod now.	Hazard Alarm	Pod and PDM	Continuous tone	Pod has been deactived. Insulin delivery stopped. Press **OK** to acknowledge. Change Pod. Check blood glucose.
Low reservoir. Replace pod soon. (This is based on the volume level you selected.)	Advisory Alarm	Pod and PDM	2 sets of beeps every minute for 3 minutes. Repeats every 60 minutes until acknowledged. Escalates to ***Empty reservoir*** hazard alarm when empty.	Press **OK** to acknowledge.
Empty reservoir. Insulin delivery stopped. Change pod now.	Hazard Alarm	Pod and PDM	Continuous tone	This alarm occurs when the Pod's reservoir is out of insulin. Press **OK** to acknowledge. Change Pod. Check blood glucose.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Pod expiration advisory. Change pod now.	Advisory Alarm	Pod	2 sets of beeps that repeat periodically. Repeats every 15 minutes during the last hour of the Pod's life and is independent of the Expiration Notification that you can set. (See Chapter 6, Using the Personal Diabetes Manager.) Escalates to ***Pod expired*** hazard alarm.	Press **OK** to acknowledge. Change Pod (see Chapter 5, Using the Pod).
Pod expired. Insulin delivery stopped. Change pod now.	Hazard Alarm	Pod	Continuous tone	This alarm occurs when the Pod has reached the end of its operating life. Press **OK** to acknowledge. Change Pod. Check blood glucose.
Stuck key detected. Check Home button to resolve. For technical support refer to your User Guide.	Advisory Alarm	PDM	2 sets of beeps every 5 minutes.	Check the key described on the screen. (In this example, the stuck key is the **Home** button.) Press the key to unstick it. If this does not work, call Customer Care.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Occlusion detected. Insulin delivery stopped. Change pod now.	Hazard Alarm	Pod	Continuous tone	Press **OK** to acknowledge. Change Pod. Check blood glucose.
Pod Error. Insulin delivery stopped. Change pod now.	Hazard Alarm	Pod or PDM	Continuous tone	This alarm occurs when the Pod detects an unexpected error. Press **OK** to acknowledge. Change Pod. Check blood glucose.
PDM Error. Remove pod now. For customer support, refer to your User Guide.	Hazard Alarm	PDM	Continuous tone	This alarm occurs if an unexpected error is detected in the PDM. Press **OK** to acknowledge. Remove Pod. Call Customer Care immediately. Check blood glucose.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
PDM Error. Memory corruption. Press "Ok" to reset PDM and delete all user settings. History records will not be deleted.	Hazard Alarm	PDM	Continuous tone	This alarm occurs after the PDM is reset and a memory corruption error occurs. Press **OK** to acknowledge. Change Pod. Check blood glucose.
System Error. Remove pod now. For customer support, refer to your User Guide.	Hazard Alarm	PDM or Pod	Continuous tone	This alarm occurs if an unexpected error is detected in the Pod or PDM. Press **OK** to acknowledge. Remove Pod. Call Customer Care immediately. Check blood glucose.
PDM Error. Press "Ok" to reset clock.	Hazard Alarm	PDM	Continuous tone	This alarm occurs after the PDM is reset, indicating that the time and date must be reset. Press **OK** to acknowledge. Reset clock. Check blood glucose.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Pod deactivation required. Press "Ok" to deactivate.	Hazard Alarm	PDM	Continuous tone	This alarm occurs after a PDM error occurs that requires the user to reset the date and time. Press **OK** to acknowledge. Change Pod. Check blood glucose.

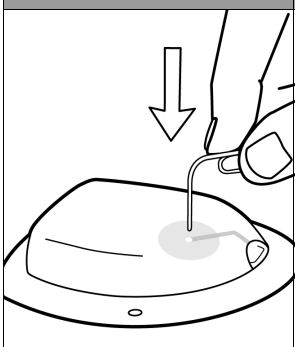
Manual Shutoff of a Hazard Alarm

If you respond to a hazard alarm but the PDM cannot communicate with the Pod to acknowledge or shut off the alarm, you can shut off the alarm manually.

1. Remove the Pod from your body if you have not already done so.
2. Press the end of a paper clip or similar item straight down into the manual alarm shut-off port (Figure 10-2) on the top side of the Pod (Figure 10-3). The port can be found by following the bright white trail on the top of the Pod. Move the paper clip back and forth until the alarm stops. Then discard the Pod according to local waste disposal regulations.

Figure 10-2

Figure 10-3



CHAPTER 11

Communication Failures

The Communication Process

When you turn on or use the Personal Diabetes Manager (PDM), it establishes communication with the active Pod. Usually, communication occurs quickly. Occasionally, communication takes longer, and the PDM displays the communication icon during that time, in the upper left hand corner of the current screen.

However, if communication does not work, the PDM will walk you through the necessary steps to re-establish communication.

Communication can fail if the PDM is:

- Too far from the Pod—It must be within 61 cm (24") when you are entering or changing settings.
- Interrupted by outside interference—See the "OmniPod System Notice Concerning Interference" in the Appendix.

Failure During Pod Activation or Operation

When you send an instruction from the PDM—such as **Start** to begin bolus delivery, or **Enable** to begin using a different basal program—the Pod usually responds quickly. However, if the PDM cannot send your instruction within a few seconds, it displays the "Communication error" screen (Figure 11-1 on the next page).

1. Move the PDM closer to the Pod. The PDM will try to communicate with the Pod again. If communication still fails, you will see the message in Figure 11-2 on the next page.

Figure 11-1

Figure 11-2

Figure 11-3

Figure 11-4

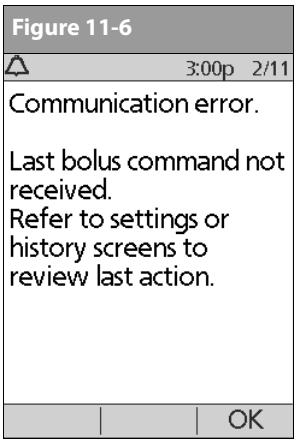
2. Move across the room or to a different room. Then press **Retry**.
   a. If you press **Retry** within 2 minutes, the PDM tries to communicate with the Pod again. If it cannot communicate, it displays the same screen as in Figure 11-2, then finally the "Communication timeout" screen (Figure 11-3). Press **OK** to check the Pod status.
   b. If the status check fails, you will see Figure 11-4. Press **OK** to try checking Pod status again, or press **Discard** to begin the deactivation process.

3. If at any point in this process the PDM can communicate again with the Pod, you will see either:
   a. Figure 11-5, indicating that your original instruction or command was successfully sent to the Pod. When you press **OK**, or within 5 seconds, the System displays the next screen in the command sequence you were entering.
   b. Figure 11-6, indicating that your last command was not sent to the Pod. Press **OK**.

      If you were activating a Pod, the System returns to the previous screen, where you can continue activation. If you were issuing any other command, the System returns to the **Status** screen, where you can reissue the command.

Figure 11-5

Figure 11-6


3:00p 2/11
Communication error.
Last bolus command not received.
Refer to settings or history screens to review last action.
OK

Failure During Pod Deactivation

To review the deactivation process, see "Deactivate the current Pod" in Chapter 5, Using the Pod.

If you press **Confirm** to deactivate the active Pod and the PDM cannot send your instruction to the Pod, you will see the screen in Figure 11-7.

Figure 11-7

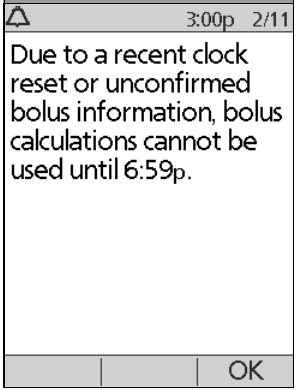
Either:

1. Press **Retry** to try deactivating the Pod again. If the PDM still cannot send the instruction, you will see Figure 11-7 again. Follow step 2.

2. Press **Discard**. The PDM will consider the Pod lost, and ask whether you want to activate a new Pod.

NOTE If you have an unconfirmed correction bolus when you discard a Pod, then the bolus calculator will be temporarily disabled. In this situation, the bolus calculator is dis-abled until the duration-of-insulin-action period passes (Figure 11-8). If you have any questions, call Customer Care.

Figure 11-8



Failure During Request for Status

If you turn on the PDM or press **Status** and the PDM cannot communicate with the Pod, it displays a communication icon (Figure 11-9). Below the icon is a soft key labeled **Skip**.

Either:

1. Wait until you see the "Pod status not available" screen (Figure 11-10).

Figure 11-9

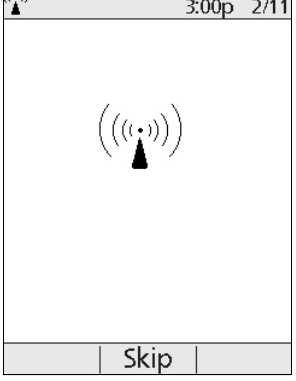
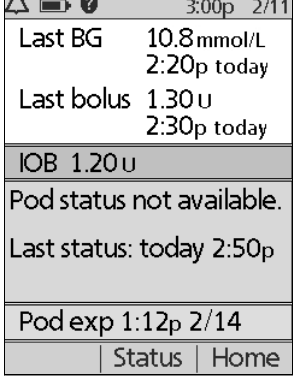


Figure 11-10



Or press **Skip** to skip the communication process and immediately bring up Figure 11-10.

NOTE If the Pod has expired, you will see the screen in Figure 11-11 instead.

Figure 11-11

At either "Pod status not available" screen, press **Home** to return to the **Home** screen, or press **Status** to send another status request.

Failure During Bolus Cancellation

When you instruct the PDM to cancel a bolus, if the PDM cannot send your instruction to the Pod within a few seconds, it displays the "Communication error" screen (Figure 11-12).

Figure 11-12

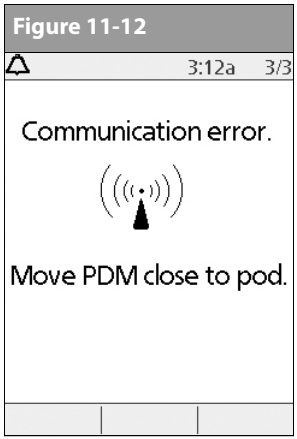
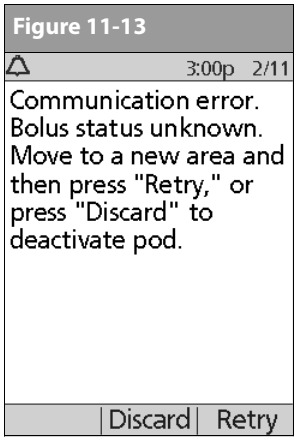


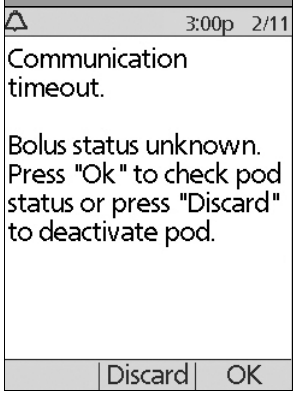
Figure 11-13



1. Move the PDM close to the Pod. The PDM tries to communicate with the Pod again.
2. If the PDM still cannot communicate with the Pod, you will see the "Bolus status unknown" message (Figure 11-13).

3. Move across the room or to a different room. Then either:
   a. Press **Discard** to begin the deactivation process.
   b. Press **Retry** to repeat the attempts to communicate with the Pod. The PDM tries to communicate with the Pod again. If it cannot communicate, it displays the same screen as in Figure 11-13, then finally a second "Bolus status unknown" screen (Figure 11-14). Press **OK** to check the Pod status or press **Discard** to begin the deactivation process.

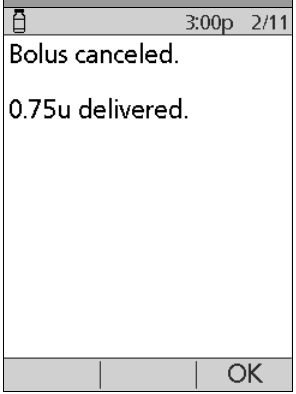
Figure 11-14


3:00p 2/11
Communication timeout.
Bolus status unknown. Press "Ok" to check pod status or press "Discard" to deactivate pod.
Discard
OK

4. If at any point in this process the PDM can communicate again with the Pod, you will see Figure 11-15. The message indicates that your original instruction to cancel the bolus was successful.
   a. Press **OK**. The PDM displays the screen in Figure 11-16, showing how much insulin was delivered before the bolus was canceled.

Figure 11-15

Figure 11-16



   b. Press **OK** again to return to the **Status** screen.

Appendix

NOTE The OmniPod Insulin Management System has no user-serviceable parts. If you require assistance operating or maintaining the System, please contact Customer Care.

Pod Care and Maintenance

Storage

Store unopened Pods in a cool, dry place. Extreme heat or cold can damage Pods and cause them to malfunction. If Pods are exposed to extreme temperatures, inspect them carefully before use. Pods are sterile unless packaging is opened or damaged. Do not apply or use a Pod if its sterile packaging is opened or damaged.

Cleaning

Pods are waterproof. If you need to clean a Pod, you can gently wash it with a clean, damp cloth. Or you can use mild soap and water. However, do not use strong detergents or solvents. They can damage the Pod's casing or irritate the *infusion site*.

CAUTION Hold the Pod securely and take care while cleaning it, so the cannula doesn't kink and the Pod doesn't become detached from your skin.

Personal Diabetes Manager Care and Maintenance

Storage

When you are not actively using the Personal Diabetes Manager (PDM) to enter or change programs, you can store it in a convenient, nearby location. The storage location should be cool and dry.

CAUTION Do not store or leave the PDM where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

If the PDM is not safe from children or others who may press the buttons by accident, consider using the optional **PDM lock** safety feature to prevent accidental program changes (see Chapter 6, Using the Personal Diabetes Manager).

Cleaning and Disinfecting

Keep your PDM test strip port and USB port free of debris and liquids. Dirt, dust, blood, and control solution may impair the functionality of your PDM or damage it.

If the battery compartment becomes solid, gently shake out the debris or use a dry, lint-free cloth to remove it.

Do NOT use IV Prep wipes, alcohol wipes, soap, detergent, or solvents. Never put any liquid into the battery compartment. The PDM is not waterproof. Do NOT immerse it or place it in or near water. Do NOT try to clean the test strip port or USB port.

Use the guidelines below to clean or disinfect your PDM:

1. Clean your PDM if it is visibly dirty. Disinfect your PDM at least once per month.
2. Be sure to turn off your PDM before cleaning or disinfecting.
3. To clean and disinfect the outside surfaces of the PDM housing, use Dispatch® Cleaner Disinfectant Towels with Bleach (Available online through major retailers) or equivalent 10% bleach disinfectant product.
4. Following the instructions on the label of the Dispatch® Cleaner Disinfectant Towels with Bleach, wipe the outside surfaces of your PDM. Treated surfaces must remain wet for a full (2) minutes.

While cleaning, do NOT allow debris or liquid to get into the test strip port, USB port, battery compartment, or buttons.

5. Let your PDM air dry completely before checking your BG next. We recommend you perform a control solution test to ensure the system functions properly. See “Performing a Control Solution Test” in Chapter 7, Checking Your Blood Glucose.
6. When finished, thoroughly wash your hands with soap and water.
7. If you require assistance, contact customer care.

Replacing batteries

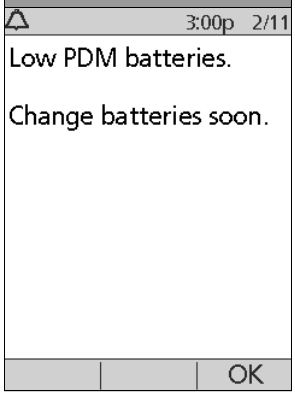
The PDM uses two (2) AAA alkaline batteries. You can purchase them at any grocery, hardware, or convenience store.

Do not use any other type of batteries than AAA alkaline batteries to power the PDM. Never use old or used batteries; the PDM may not work properly. Using any kind of batteries other than alkaline may reduce battery life and cause damage to the PDM.

A pair of AAA alkaline batteries powers the PDM for approximately 3 weeks. The battery life indicator on the PDM shows the battery power level.See “Personal Diabetes Manager Icons” on page 148 for the various battery power levels and their respective icons.

The PDM automatically alerts you when its battery power gets low (see Figure A-1). When you see the "Low PDM battery" alert, press **OK** to turn off the alert. Replace the batteries as soon as you can.

Figure A-1



NOTE

When your PDM alerts you that battery power is getting low, the PDM will maximize remaining battery life by:

- Turning off your vibration alert (if set)
- Disabling bright mode
- Disabling the test strip port light

Once the batteries are replaced, these functions resume.

CAUTION

If the batteries run out, data in the memory is at risk. DO NOT remove the old batteries until you have new ones at hand. The PDM protects data in the memory for up to 2 hours after the batteries run out or are removed.

To replace batteries

1. Open the battery compartment on the back of the PDM by pushing the compartment latch inward and then upward (Figure A-2). No special tools are necessary.

Figure A-2

2. Insert 2 new AAA alkaline batteries into the compartment.

NOTE The diagram inside the compartment shows you which direction to insert the batteries.

3. Replace the battery door.
4. Turn the PDM face up. The PDM powers on automatically.

The PDM is now ready to use. Dispose of the old batteries in accordance with local waste disposal regulations.

If the PDM becomes submerged in water

The PDM is not waterproof. Do not place it in water or leave it near water where it can accidentally fall in. If it becomes submerged in water:

1. Dry the outside of the PDM with a clean, lint-free cloth.
2. Open the battery compartment; remove the batteries and discard them.
3. Use a clean, lint-free cloth to gently absorb any water in the battery compartment.
4. Leave the battery compartment door open until the PDM is thoroughly dry.

CAUTION Never use a blow dryer or hot air to dry the Pod or PDM. Extreme heat can damage the electronics.

5. Do not put in fresh batteries or attempt to use the PDM until it has thoroughly air-dried.

If you drop the PDM

The PDM is built to withstand reasonable amounts of abuse, but shock or a severe impact can damage it. If you drop the PDM or if it is otherwise subjected to severe impact:

1. Inspect the outside of the PDM for visible signs of damage.
2. Press and hold the **Power** button to see whether the PDM turns on and whether the LCD screen is damaged.
3. Inspect the inside of the battery compartment for visible signs of damage.
4. Do NOT use the PDM if it appears damaged or is not working as it should.

NOTE If you require assistance, contact Customer Care.

Storage and Supplies

Storage

Store all OmniPod System products and supplies (including unopened Pods) in a cool, dry place. Products or supplies that have been exposed to extreme temperatures may not function properly.

It is especially important to store your *insulin* in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated, or inactive. Check the insulin manufacturer's instructions for use and expiration date.

Ordering supplies

You can order all OmniPod System products and supplies by contacting Customer Care at 1 855 POD INFO (1 855 763 4636). When outside of Canada, please call 647-788-3132.

Suggested Bolus Calculator Examples and Guidelines

A suggested bolus is equal to the sum of a correction bolus and meal bolus, then adjusted for insulin on board (IOB), if applicable. Examples of each of these elements are shown below.

Example of correction bolus

Target BG: 5.6 mmol/L
Current BG: 11.2 mmol/L
Correction factor (CF): 2.8

11.2 mmol/L (current) – 5.6 mmol/L (target) = 5.6 mmol/L

5.6 mmol/L ÷ 2.8 (CF) = 2 units *correction bolus*

If the *reverse correction* feature is turned **On** and if your current BG is below your target BG, the suggested bo)lus calculator subtracts a correction amount from the meal bolus.

Example of reverse correction bolus:

Target BG: 5.6 mmol/L
Current BG: 4.2 mmol/L
Correction factor (CF): 2.8

4.2 mmol/L (current) – 5.6 mmol/L (target) = –1.4 mmol/L

–1.4 mmol/L ÷ 2.8 CF = –0.5 units reverse correction bolus (reduces meal bolus)

Meal bolus calculation

Carbs entered ÷ insulin-to-carb (I/C) ratio

Example of meal bolus

Carbs entered: 45 grams of carb
Insulin-to-carb ratio: 15

45 carbs ÷ 15 I/C ratio = 3 units meal bolus

Insulin-on-board (IOB) calculation

(*Duration of insulin action* – time since your previous bolus) ÷ (duration of insulin action) * (previous bolus)

IOB from a previous correction bolus is called "correction IOB," and IOB from a previous meal bolus is called "meal IOB."

Example of correction IOB

Duration of insulin action: 3 hours
Time since previous correction bolus: 1 hour
Previous correction bolus: 3 units

3 hours – 1 hour = 2 hours

2 hours ÷ 3 hours = 2/3

2/3 * 3 units = 2 units correction IOB

In other words, one hour after your previous correction bolus, you have received only 1 unit of insulin from it; 2 units of insulin are still working to correct your BG. This feature prevents delivering too much insulin when correcting a high BG.

Example of meal IOB

Duration of insulin action: 3 hours
Time since previous meal bolus: 2 hours
Previous meal bolus: 4.5 units

3 hours – 2 hours = 1 hour

1 hours ÷ 3 hours = 1/3

1/3 * 4.5 units = 1.5 units meal IOB

In other words, two hours after your previous meal bolus, you have received 3 units of insulin from it; 1.5 units of insulin are still working to cover your meal.

Meal IOB is only used to reduce a correction bolus, and the correction bolus is only reduced until it becomes 0 units.

Examples of suggested bolus calculations

The examples below use these settings:

- Target BG: 5.6 mmol/L
- I/C ratio: 1:15
- Correction factor (CF): 2.8
- Duration of insulin action: 3 hrs

Example 1

Current BG level: 8.4 mmol/L
Carb intake: 0 grams of carbohydrate (carbs)
Meal IOB: 1 units
Correction IOB: 1 units

Correction bolus: 8.4 mmol/L (current) – 5.6 mmol/L (target) = 2.8

2.8 ÷ 2.8 (CF) = 1 unit

Meal bolus: 0 (carbs) ÷ 15 (I/C ratio) = 0 units

Suggested bolus dose = 1 (correction) + 0 (meal) – 2 (IOB) = 0U

Example 2

Current BG level: 8.4 mmol/L
Carb intake: 45 carbs
Meal IOB: 0 units
Correction IOB: 0 units

Correction bolus: 8.4 mmol/L (current) – 5.6 mmol/L (target) = 2.8

2.8 ÷ 2.8 (CF) = 1 unit

Meal bolus: 45 (carbs) ÷ 15 (I/C ratio) = 3 units

Suggested bolus dose = 1 (correction) + 3 (meal) – 0 (IOB) = 4U

Example 3

Current BG level: 5.6 mmol/L
Carb intake: 45 carbs
Meal IOB: 1 units
Correction IOB: 0 units

Correction bolus: 5.6 mmol/L (current) – 5.6 mmol/L (target) = 0

0 ÷ 50 (CF) = 0 units

Meal bolus: 45 (carbs) ÷ 15 (I/C ratio) = 3 units

Suggested bolus dose = 0 (correction) + 3 (meal) – 0 (IOB) = 3U

NOTE

Meal IOB is never subtracted from another meal bolus—only from a correction bolus.

Example 4

Current BG level: 8.4 mmol/L
Carb intake: 60 carbs
Meal IOB: 0 units
Correction IOB: 1 unit

Correction bolus: 8.4 mmol/L (current) – 5.6 mmol/L (target) = 2.8

2.8÷ 2.8 (CF) = 1 unit

Meal bolus: 60 (carbs) ÷ 15 (I/C ratio) = 4 units

Suggested bolus dose = 1 (correction) + 4 (meal) – 1 (IOB) = 4U

Calculator guidelines

When the suggested bolus calculator is turned **On**, the OmniPod System applies these guidelines to the suggested bolus doses:

- Suggested bolus doses are rounded down to the nearest 0.05U.
- If the total of the suggested bolus calculation (correction bolus plus meal bolus) is less than zero, the suggested bolus dose is 0.00U.
- The System will not suggest a bolus dose if your current blood glucose (BG) reading is below the minimum BG you have set for bolus calculation (see Chapter 2, Getting Started, and Chapter 6, Using the Personal Diabetes Manager).
- The System suggests a correction bolus only when your BG reading is above the *correction threshold* or correct-above value you have set (see Chapter 2, Getting Started, and Chapter 6, Using the Personal Diabetes Manager).
- Meal IOB, which is insulin on board (IOB) from a previous meal bolus, is subtracted first from the current correction bolus, if any, until it is zero. However, any remaining meal IOB is *never* subtracted from the current meal bolus.
- Correction IOB, which is insulin on board (IOB) from a previous correction bolus, is then subtracted from the current correction bolus, if any remains, until it is zero. At that point, any remaining correction IOB is subtracted from the current meal bolus.
- The calculated insulin on board (IOB) is rounded up to the nearest 0.05U.
- A reverse correction only occurs if the meal bolus is greater than 0.00U.
- If your blood glucose value is below the target blood glucose value and you have set *reverse correction* to **On,** the suggested correction bolus is subtracted from the suggested meal bolus. If you have set reverse correction to **Off**, the System will not subtract insulin from the suggested meal bolus dose.
- If you manually increase or decrease the suggested bolus, the following rules apply:
- If you increase a suggested bolus, the increase is applied to the meal bolus unless there is no meal bolus, in which case it is applied to the correction bolus.
- If you decrease a suggested bolus, the decrease is applied to the meal bolus until it reaches zero; then it is applied to the correction bolus. If there is no meal bolus, the decrease is applied to the correction bolus.

OmniPod System Options and Settings

Time	12-hour or 24-hour clock
Date	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Maximum basal rate	30 U/hr Default is 3.00 U/hr
Basal programs	7
Basal rate segments	24 per program
Basal rate increment	0.05 units
Temp basal presets	7
Temp basal	%, Units, or Off 30 minutes to 12 hours in 30-minute increments Default is Off
Blood glucose (BG) goal for BG history	Upper and lower limits; 3.9 to 11.1 mmol/L in 0.1 mmol/L increments
Blood glucose reminder	On or Off; maximum of 4 Reminder time of 1 to 4 hours after every bolus dose in 30-minute increments Default is Off
Blood glucose meter sound	On or Off Default is On
Suggested bolus calculator	On or Off Default is On
Target BG value and correction threshold	4 time segments; 3.9 to 11.1 mmol/L in 0.1 mmol/L increments
Minimum BG allowed for use by the suggested bolus calculator	2.8 to 3.9 mmol/L in 0.1 mmol/L increments Default is 3.9 mmol/L
Insulin-to-carb (IC) ratio	4 time segments; 1 to 150 g carb/U in 1g carb/U increments
Correction (sensitivity) factor	4 time segments; 0.1 to 16.7 mmol/L in 0.1 mmol/L increments
Reverse correction	On or Off Default is On
Duration of insulin action	2 to 6 hours in 30-minute increments
Bolus increment	0.05, 0.1, 0.5, or 1.0 units Default is 0.1 units
Maximum bolus size	30 units Default is 10 units
Extended bolus	%, Units, or Off 30 minutes to 8 hours in 30-minute increments Default is Off
Bolus presets	7
Carbohydrate presets	36

Suspend	30 minutes to 2 hours
Low reservoir volume indicator	10 to 50 units in 5-unit increments Default is 10.0 units
Pod expiration alert	1 to 24 hours in 1-hour increments Default is 4 hours
Auto-off alert	1 to 24 hours or Off in 1-hour increments Default is Off
PDM lock	On or Off Default is Off
History storage	5400 records/90 days
Language	English

Pod Specifications

Size: 4.1cm x 6.2cm x 1.7cm
(1.6" wide x 2.4" long x 0.7" high)

Weight (with full reservoir): 34 grams (1.2 oz)

Operating temperature range: 5° C to 40° C (40° F to 104° F)
Under normal circumstances, your body temperature will keep the Pod well within this range.

Startup temperature: above 10° C (50° F)

Storage temperature range: -10° C to 50° C (14° F to 122° F)

Reservoir volume (deliverable): 200 units

Cannula insertion depth: 6.5 mm

Waterproof rating: IPX8 (7.6 m (25') for 60 minutes)

Insulin concentration: U-100

Alarm type: Audible

Operating relative humidity range: 20–85%, noncondensing

Storage relative humidity range: 20–85%, noncondensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Flow Capability:

Basal: Programmable by the user in 0.05U pulses up to 30.0 U per hour

Bolus:

Rate: 1.5 units per minute

Range: 0.05 to 30.0 units

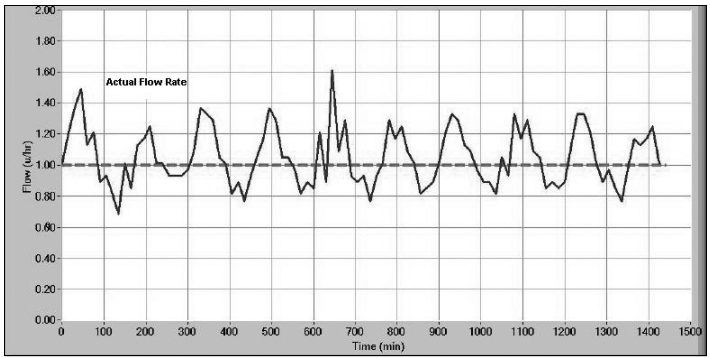
Delivery accuracy (tested per IEC 60601-2-24):
Basal: +/- 5% at rates > 0.1 U/hr
Bolus: +/- 5% for all set values > 0.1 units

Accuracy Test Results

The following graphs are designed to show flow accuracy of the Pod against given time periods.

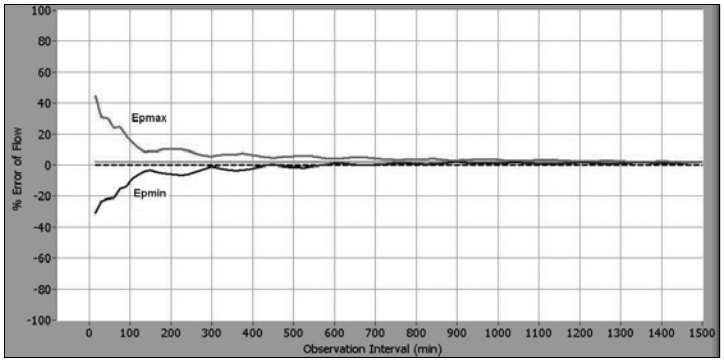
Flow rate from startup

The following graph shows changes in the flow rate over the stabilization period. The measurements were made using a Pod with a basal rate of 1.0 U/h at high operating temperature.



Flow rate error

The following trumpet curve shows the accuracy of the delivery rate in relation to the observation period. The measurements were made using a Pod with a basal rate of 1.0 U/h at high operating temperature. The overall mean percentage flow error was 1.94%.



Personal Diabetes Manager Specifications

Size: 6.4 cm x 11.4 cm x 2.5 cm (2.5" wide x 4.5" long x 1.0" high)

Weight (with batteries): 125 grams (4.4 oz)

Screen: 3.6 cm x 4.8 cm (1.4" wide x 1.9" long); 6.1cm diagonal (2.4") LCD

Battery: Powered by 2 AAA alkaline batteries

Battery life: Approximately 3 weeks

Operating temperature range: 5° C to 40° C (40° F to 104° F)

Storage temperature range: -10° C to 50° C (14° F to 122° F)

Operating relative humidity range: 5% to 90% noncondensing

Storage relative humidity range: 5% to 90% noncondensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: Up to 61 cm (24")

Alarm type: Audible

Alert type: Audible and Vibratory (Optional)

Blood Glucose Meter Specifications

Assay method: Coulometric electrochemical sensor

Calibration: Plasma equivalent

Hematocrit: 15% to 65%

Measurement units: mmol/L

Result range: 1.1 to 27.8 mmol/L

Sample: Whole blood, capillary

Sample size: 300 nanoliters (0.3 microliter)

Test time: Results as fast as 7 seconds

OmniPod System Label Symbols

Symbol	Meaning
	Do not reuse this device; single-use only
	Caution: Consult accompanying documents
	Refer to instruction manual
STERILE EO	Sterilized by ethylene oxide
LOT	Lot number
No Symbol	Expiration date (use-by date): (yyyy-mm-dd)
REF	Reference/reorder number
SN	Device serial number
	Type BF medical device (protection from electrical shock)
	Non-pyrogenic; fluid pathway only
	Not MRI-safe
IPX8	Waterproof to 7.6 m (25') for 60 minutes
	Keep dry

Symbol	Meaning
	Storage temperature
	Do not use if package is damaged
CE 0344	Product is designed and manufactured in accordance with applicable standards/guidelines and may be sold in the EU (European Union).
Hg	Do not throw away; contains mercury.

Personal Diabetes Manager Icons

Icon	Meaning	Icon	Meaning
	Power		More actions
	Bolus		Communication
	Pod change		Up/Down
	Diagnostics/ settings		Up/Down (on color)
	Temp basal		Status

Icon	Meaning	Icon	Meaning
	Suspend/cancel		Text entry right
	My Records		Submenu
	Advisory alarm		Home screen
	(alternating) Hazard alarm		Insulin gauge
	Alert		Apply blood sample/ Blood glucose records
	PDM lock		Setup Wizard
	Battery 3/4 full		Battery full
	Battery 1/4 full		Battery half full
	Basal program		Battery empty
	"Lost" history record		User Information/ Support
	"Unconfirmed" history record		Temperature out of range
	"Delivery Spans Midnight" history record		Active/default program or selected BG tag

OmniPod System Notice Concerning Interference

The OmniPod Insulin Management System (both the Pod and the Personal Diabetes Manager or PDM) complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

Changes or modifications not expressly approved by Insulet could void the user's authority to operate the equipment.

Both the Pod and the PDM generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the OmniPod System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the OmniPod System.
- Increase the distance between the OmniPod System and the other device that is emitting or receiving interference.

Insulet Corporation declares that the OmniPod System is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. This ISM device complies with Canadian ICES-003 and IC-RSS-210.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the OmniPod System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use.

Portable and mobile RF communications equipment can affect medical electrical equipment.

This ISM device complies with Canadian ICES-003 and IC-RSS-210.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the System should be observed to verify normal operation in this setting.

The System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The OmniPod System communicates with the following characteristics:

Frequency: 13.56 Mhz, ASK modulation, with an effective radiated power of 16mW

The OmniPod System greatly exceeds the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
Emissions	**Compliance according to**	**Electromagnetic environment**
RF Emissions (CISPR 11)	Group 2	The Pod and the PDM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 6 kV air discharge: ± 8 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power Frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	3 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.

Electromagnetic Immunity (Continued)			
Conducted RF (IEC 61000-4-6) Radiated RF (IEC 61000-4-3)	3 Vrms 150 kHz to 80 Mhz 80 MHz–2.5 GHz	3 V/m 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended separation distance: $d=1.17\sqrt{P}$ $d=0.35/\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Recommended separation distances between portable and mobile RF communications equipment and the System

You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, in watts	**Separation distance according to frequency of transmitter, in meters**		
	150 kHz to 80 MHz, d = 1.17 √P	*80 MHz to 800 MHz, d = 0.35 √P*	*800 MHz to 2.5 GHz, d = 0.7 √P*
0.01	0.12	0.035	0.070
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.70	1.11	2.21
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Limited Warranty for the Personal Diabetes Manager

Limited Warranty Coverage

Insulet Corporation (the manufacturer of the OmniPod™ system) warrants to the original end-user ("you") that the Personal Diabetes Manager (the "PDM") will be free from defects in materials and workmanship, under normal use and conditions, for a period of five (5) years from the date of delivery. If Insulet Corporation determines that the PDM is defective during the warranty period, Insulet Corporation will either repair or replace, at its option, the PDM at no charge to you, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the PDM is repaired or replaced, the warranty period shall not be extended.

Warranty Claim Procedure

You must notify Insulet Corporation of the claimed defect within the warranty period by calling the Canadian customer care line at: 1-855-PODINFO (763-4636) maintained by the Canadian distributor of OmniPod™ in Canada, GlaxoSmithKline Inc. The claim must include the date of purchase, model number, serial number, and a description of the claimed defect. Insulet Corporation's authorization must be obtained prior to returning the PDM. If authorized, the PDM must be properly packaged and returned to Insulet Corporation. Insulet Corporation will pay all freight and transportation charges, where applicable, incurred in shipping a PDM to be repaired or replaced under this Warranty. Coordination and further direction of this return shipment can be provided for by calling the Canadian customer care line at: 1-855-PODINFO (763-4636).

Conditions

Proof of Purchase in the form of a bill of sale or receipted invoice showing that the PDM is within the warranty period must be presented to obtain warranty service.

Exclusions

This Warranty covers only the original end-user and cannot be transferred with sale, rental or other transfer of the PDM to any other person or entity.

THIS WARRANTY DOES NOT APPLY IF THE PDM HAS BEEN:

- changed or modified by any person or entity other than Insulet Corporation;
- serviced or repaired by any person or entity other than Insulet Corporation; or damaged by an act of God, misuse, abuse, negligence, accident, wear and tear, unreasonable use, or by other causes unrelated to defective materials or workmanship.

Miscellaneous

REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS YOUR EXCLUSIVE REMEDY. ANY APPLICABLE IMPLIED WARRANTIES OR CONDITIONS, INCLUDING WARRANTIES AND CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, OR ITS DISTRIBUTORS BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY OR CONDITION ON THE PDM. Some jurisdictions do not allow limitations on how long an implied warranty or condition lasts, and some jurisdictions do not allow the exclusion or limitation of consequential or incidental damages, so the above limitations or exclusions may not apply to you. This Warranty gives you specific legal rights, and you may also have other rights which vary from jurisdiction to jurisdiction. This Warranty is valid only in the United States and Canada.

No Other Warranty

This Warranty is understood to be the complete and exclusive warranty for the PDM. No employee of Insulet Corporation, GlaxoSmithKline Inc. or any other party is authorized to make any warranty in addition to those made in this Warranty.

Privacy Code

GlaxoSmithKline Inc. and Insulet Corporation (collectively, "GSK") are committed to the protection of the personal information of individuals with whom it comes into contact. Accordingly, GSK adheres to the principles of its Privacy Code, which is based on and incorporates principles set out in Schedule 1 of the *Personal Information Protection and Electronic Documents Act*, Canada (PIPEDA). GSK complies with all relevant provisions of PIPEDA. GSK's Privacy Code is available on-line at www.gsk.ca.

You and Your Healthcare Provider

The contents of the OmniPod® user manual are not intended to replace or substitute the advice of your physician or other qualified healthcare professionals. You should speak to your own healthcare professional, who is the best source of information regarding your own health related questions. Absolutely no information contained in the OmniPod® user manual should be construed as taking the place of your physician's or other qualified healthcare professional's advice.

Glossary

A1c (see Hemoglobin A1c)

Advisory alarm
Notification by the PDM that a serious condition exists.

Aseptic technique
A method for maintaining sterilization and preventing contamination.

Basal program
One or more *basal rates* that together cover a 24-hour period from midnight to midnight.

Basal rate
A small base or background amount of *insulin* that is delivered, at a preset rate, continuously for a specified period of time. Basal rates are measured in units per hour (U/hr).

Basal segment (time segment)
The time period during which a specific *basal rate* is delivered.

BG goal
A range of *blood glucose levels* that you are trying to achieve during a certain period of the day. For example, you may want one BG goal before meals, a different BG goal two hours after meals, and yet another BG goal for bedtime.

Blood glucose (see glucose)

Blood glucose level
The amount of *glucose*, or sugar, in the blood.

Blood glucose meter
A device used to check blood *glucose* content.

Bolus dose
A dose of insulin taken to correct an elevated *blood glucose level* or to cover *carbohydrates* in a meal or snack.

Bolus preset
A *bolus dose* of insulin, in units, that can be assigned a custom name and preprogrammed into the PDM.

Calorie
A unit of measurement used to express the energy value of food. Calories come from carbohydrate, protein, fat, and alcohol.

Cannula
A small, thin tube inserted below the skin, which serves to introduce a liquid medication into the body.

Carbohydrate (carb)
One of the three main nutrients found in food. (The other two are *protein* and *fat*.) Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

Carbohydrate counting
A method of meal planning based on counting the number of grams of carbohydrate in a given food.

Carb preset
A favorite food item, snack, or entire meal that can be assigned a custom name and preprogrammed into the PDM. You set the carbohydrate value (and, optionally, the fat, protein, fiber, and total calories) for each carb preset.

Complications (of diabetes)
Harmful effects of diabetes such as damage to the eyes, kidney, heart, blood vessels, nervous system, teeth and gums, feet, and skin.

Correction bolus
An amount of *insulin* taken to compensate for high *blood glucose levels*. The OmniPod System calculates the correction bolus by taking the difference between your current blood glucose level and your *target blood glucose value*, then dividing the result by your *correction factor*.

Correction factor (also known as sensitivity factor)
A value that indicates how much one unit of *insulin* will lower your *blood glucose*. For example, if your correction factor is 2.8, one unit of insulin will lower your blood glucose by 2.8 mmol/L.

Correction threshold
The *blood glucose level* above which you would like to take insulin to reduce an elevated blood glucose.

CSII (continuous subcutaneous insulin infusion)
Delivering insulin continuously under the skin ("*subcutaneously*") on a programmed schedule.

Dawn phenomenon
An early morning rise in blood glucose level caused by the normal release of hormones that block insulin's effect.

Diabetes Control and Complications Trial (DCCT)
A study by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), conducted from 1983 to 1993 in people with type 1 *diabetes*, which showed that good *blood glucose* control significantly helped prevent or delay diabetes *complications*.

Diabetes, diabetes mellitus
A condition characterized by *hyperglycemia* (high *blood glucose*) resulting from the body's inability to use *blood glucose* for energy. In type 1 diabetes, the pancreas no longer makes *insulin* and therefore blood glucose cannot enter the cells to be used for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly.

Diabetic ketoacidosis (see Ketoacidosis)

Duration of insulin action
The length of time that certain types of *insulin* remain active and available in your body after a *bolus*. This duration can vary greatly depending on the type of insulin you take. Only use rapid-acting insulin with the OmniPod Insulin Management System.

Extended bolus
A feature of the OmniPod System that allows a meal *bolus dose* to be given over an extended period of time.

Fat
One of the three main energy sources in food (the other two are *carbohydrate* and *protein*). Fat is a concentrated source of energy, providing 9 calories per gram. Foods high in fat include oils, margarine, salad dressings, red meat, and whole-milk dairy foods.

Fibre
The indigestible part of plant foods. Foods that are high in fiber include broccoli, beans, raspberries, squash, whole grain bread, and bran cereal. Fiber is a type of *carbohydrate* but does not raise *blood glucose levels* as other carbohydrates do.

Glucose
A simple sugar (also known as dextrose) used by the body for energy. Without *insulin*, the body cannot use glucose for energy.

Hazard alarm
Notification by the PDM that a dangerous condition exists.

Healthcare provider
A professional who practices medicine or teaches people how to manage their health. All healthcare providers are a resource for valuable diabetes management information.

Hemoglobin A1c (HbA1c)
A test that measures a person's average *blood glucose level* over the past 2 to 3 months. Also called glycosylated hemoglobin, the test shows the amount of *glucose* that sticks to the red blood cell, which is proportional to the amount of glucose in the blood.

Hyperglycemia (high blood glucose)
A higher-than-normal level of *glucose* in the blood; generally 10.0 mmol/L or higher.

Hypoglycemia (low blood glucose)
A lower-than-normal level of *glucose* in the blood; generally 3.9 mmol/L or lower.

Hypoglycemia unawareness
A condition in which a person does not feel or recognize the symptoms of *hypoglycemia*.

Infusing
Introducing a liquid substance under the skin into the body.

Infusion site

Place on the body where an infusion set or Pod is placed and cannula is inserted.

Insulin

A hormone that helps the body use *glucose* for energy. The beta cells of a healthy pancreas make insulin.

Insulin on board (IOB) - (active insulin)

The amount of *insulin* that is still "active" in the body from a previous *bolus* dose. In the OmniPod System, insulin on board (IOB) is considered in two parts: the IOB from a previous *correction bolus* and the IOB from a previous *meal bolus*.

The amount of time insulin remains "on board" or "active" depends on each individual's *duration of insulin action*. Talk with your *healthcare provider* to determine your duration of insulin action.

The OmniPod System continually calculates the IOB to help prevent "stacking" of bolus doses, which is a major cause of *hypoglycemia*.

Insulin reaction (see hypoglycemia

Insulin-to-carbohydrate ratio (IC)

Number of grams of *carbohydrate* covered by one unit of *insulin*. For example, if your insulin-to-carbohydrate ratio is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

In vitro

Literally, "in glass." Refers to a biological function taking place in a laboratory dish rather than in a living organism.

Ketoacidosis (diabetic ketoacidosis or DKA)

A very serious condition in which extremely high *blood glucose levels* and a severe lack of *insulin* cause the body to break down *fat* for energy. The breakdown of fat releases *ketones* into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.

It is important to rule out ketoacidosis when you experience symptoms that might otherwise indicate the flu.

Ketones

Acidic by-products that result from the breakdown of *fat* for energy. The presence of ketones indicates that the body is using stored fat and muscle (instead of *glucose*) for energy.

Meal bolus (also known as carbohydrate bolus)

An amount of *insulin* administered before a meal or snack to ensure that *blood glucose levels* stay within the desired BG goal after a meal. The OmniPod System calculates a meal bolus by dividing the grams of carbohydrates you are about to eat by your *insulin-to-carbohydrate ratio*.

Multiple daily injections (MDIs)

Introducing *insulin* into the body with a syringe several times a day.

Occlusion

A blockage or interruption in *insulin* delivery.

Prime bolus

An amount of *insulin* used to fill the *cannula*, preparing it to begin delivering insulin under your skin.

Protein

One of the three main energy sources in food (the other two are *carbohydrate* and *fat*). Protein is necessary for the growth, maintenance, and repair of body cells and tissues. Protein contains 4 calories per gram. Foods high in protein include meat, poultry, fish, legumes, and dairy products.

Reverse correction (negative correction)

Using an individual's *correction factor (sensitivity factor)*, the reverse correction is a calculation that reduces a portion of a meal *bolus dose* when the patient's *blood glucose level* is below their *blood glucose target*. This feature is an option in the OmniPod Insulin Management System, which should be turned on or off according to the advice of a *healthcare provider*.

Sensitivity factor (see correction factor)

Sharps

Any medical item that may cause punctures or cuts to those handling them. Sharps include needles, syringes, scalpel blades, disposable razors, and broken medical glassware. Dispose of used sharps according to local waste disposal regulations.

Sharps container

A puncture-proof container used for storage and disposal of used *sharps*.

Soft key

A button on the PDM whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing.

Subcutaneous

Under the skin.

Suggested bolus calculator

A feature that calculates bolus doses with user-specific settings and inputs. The settings used to calculate a suggested bolus are *target BG*, *insulin-to-carbohydrate (IC) ratio*, *correction factor* (CF), and *duration of insulin action*. The inputs used to calculate a suggested bolus are current BG, carbs entered, and *insulin on board*. The bolus calculator can be turned **Off** or **On** in the PDM.

Target blood glucose level

The ideal number at which you would like your *blood glucose level* to be. The OmniPod System uses this number in calculating *bolus doses*.

Temp basal

A *basal rate* that is used to cover predictable, short-term changes in basal *insulin* need. Temporary rates are often used during exercise and for sick-day insulin adjustments.

Temporary basal preset

An adjustment in a *basal rate*, in either % or U/hr, that can be assigned a custom name and preprogrammed into the PDM.

Time segment (see basal segment)

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My PDM Settings

Use this form to keep track of your important PDM settings. Remember to update your information as you change or add settings.

Basal Program 1	
Name _____	**Rate**
12:00 AM to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr

Basal Program 2	
Name _____	**Rate**
12:00 AM to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr

Target BG		
Target BG ("correct to" values) for each time segment defined, starting at midnight. These values are used by the suggested bolus calculator.	**Target BG**	**Suggest correction when BG is above**
12:00 AM to _____	_____	_____ mmol/L
_____ to _____	_____	_____ mmol/L
_____ to _____	_____	_____ mmol/L
_____ to _____	_____	_____ mmol/L

Insulin-to-Carbohydrate Ratio	
Insulin-to-carbohydrate ratio for each time segment defined, starting at midnight.	**1 unit of insulin covers**
12:00 AM to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb

My PDM Settings

Duration of Insulin Action	
Time that insulin will remain "active" in the body from a previous bolus.	_____ hrs

Correction Factor	
Correction factor for each time segment defined, starting at midnight.	**1 unit of insulin decreases BG by**
12:00 AM to _____	_____ mmol/L
_____ to _____	_____ mmol/L
_____ to _____	_____ mmol/L
_____ to _____	_____ mmol/L

Temp Basal Presets	
Name	**Rate (circle measurement)**
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %

Bolus Presets	
Name	**Units**
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U

Carb Presets	
Name	**Grams of carbohydrate**
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

Notes

Notes

Notes

Notes

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OmniPod®

Insulin Management System
Système de gestion de l'insuline

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Model: **CAT35E**

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